

Contains Nonbinding Recommendations

510(k) Third Party Review Program

Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations

Document issued on March 12, 2020

The draft of this document was issued on September 14, 2018

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0375 (expires 11-30-2022).

See additional PRA statement in Section XI of the guidance.

This guidance supersedes “Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties” issued on February 2, 2001, and “Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications” issued on September 28, 2004.



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to <https://www.regulations.gov> . Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2016-D-2565. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 1500013 and complete title of the guidance in the request.

Table of Contents

I. Introduction	4
II. Background	5
A. Basis for 3P510k Review Program	5
B. General Overview of 3P510k Review Program	6
III. Scope	7
IV. Definitions	8
V. Factors Used in Determining Device Type Eligibility in the 3P510k Review Program	10
VI. Review of 510(k) Submissions by 3P510k Review Organizations	13
A. Determine device eligibility for 3P510k review	13
B. Assign a Product Specialist(s) and Technical Expert(s) to conduct the substantive review of a 510(k) submission	14
C. Obtain relevant FDA guidance(s) and information	14
D. Early Interaction with FDA (as needed)	16
E. Ensure a submission is administratively complete	17
F. Conduct the substantive review of a 510(k) submission	18
G. Identify deficiencies in a 510(k) submission	18
H. Document a 510(k) review	19
I. Organize and submit a 510(k) submission including associated 3P510k review documentation	20
J. Submit additional information upon FDA's request	22
K. 510(k) submission dispute resolution	23
VII. Requirements and Recommendations for Recognition and Rerecognition of Third Party Review Organizations	24
A. Operational considerations	25
B. Management of impartiality	25
C. Personnel involved in reviewing activities	27
D. Use of external Technical Experts	28
E. Confidential information	29
F. Complaints regarding 510(k) Submitters	29
G. Third Party Review Organization recordkeeping	30
VIII. Content and Format of an Application for Initial Recognition and Rerecognition as a 3P510k Review Organization	31
A. Initial Recognition	31
(1) Administrative information	32
(2) Prevention of conflicts of interest	33
(3) Personnel qualifications	33
(4) Certification statements	34
B. Rerecognition	35
C. Recognition or Rerecognition Denial	35
IX. Suspension or Recognition Withdrawal	36
X. Leveraging the International Medical Device Regulators Forum's (IMDRF's) documents	37
XI. Paperwork Reduction Act of 1995	38

510(k) Third Party Review Program

Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The 510(k) Third Party (3P510k) Review Program (formally known as the Accredited Persons (AP) Program) is authorized under section 523 of the Federal Food, Drug, and Cosmetic (FD&C) Act.¹ Under this authority, FDA recognizes third parties to review premarket notification (510(k)) submissions and recommend the initial classification of certain devices. FDA's implementation of section 523 establishes a process for recognition of qualified third parties to conduct the initial review of 510(k) submissions for certain low-to-moderate risk devices eligible for review under the 3P510k Review Program within the Center for Devices and Radiological Health (CDRH).² This guidance document also reflects amendments made to section 523 by the FDA Reauthorization Act of 2017 (FDARA),³ which directed FDA to issue guidance⁴ on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person.

For the current edition of the FDA-recognized standards referenced in this document, see the [FDA Recognized Consensus Standards Database](#).⁵ For more information regarding use of

¹ Section 523 of the FD&C Act uses the terms "accredited persons," "accredit," "accredited," "accreditation," "reaccredit," "reaccredited," and "reaccreditation." The guidance does not use those statutory terms but rather defines such terms as "recognition," and "rerecognition" as synonymous terms. These alternative terms are used in this guidance to harmonize the terms used by FDA and in the FD&C Act with those in the International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP) documents and are defined in Section IV of this guidance.

² Currently, the Center for Biologics Evaluation and Research does not regulate devices of the types subject to this guidance.

³ Pub. L. 115-52

⁴ See section 523(a)(3)(B) of the FD&C Act.

⁵ Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

Contains Nonbinding Recommendations

consensus standards in regulatory submissions, please refer to FDA guidance entitled, “Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices”.⁶

The objectives of this guidance are:

1. To describe the factors FDA will use in determining device type eligibility for review by 3P510k Review Organizations
2. To outline FDA’s process for the recognition, rerecognition, suspension, and withdrawal of recognition for 3P510k Review Organizations
3. To ensure consistent quality of work among 3P510k Review Organizations through the Medical Device User Fee Amendments (MDUFA) IV commitments authorized under FDARA⁷ to eliminate the need for routine, substantive re-review by FDA.⁸

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

A. Basis for 3P510k Review Program

On August 1, 1996, FDA launched a voluntary third party 510(k) review pilot program for selected medical devices. Under this pilot program, all class I devices that were not 510(k) exempt at that time, and 30 class II devices were eligible for 3P510k review.

On November 21, 1997, the Food and Drug Administration Modernization Act (FDAMA) was signed into law. Section 210 of FDAMA⁹ codified and expanded the pilot program by establishing section 523 of the FD&C Act.

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA)¹⁰ was signed into law and required FDA to establish and publish criteria to accredit, reaccredit, and deny reaccreditation of 3P510k Review Organizations that perform 510(k) reviews of eligible devices.

⁶ See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

⁷ Pub L. 115-52

⁸ See [Eliminating Routine FDA Re-Review of Third Party 510\(k\) Reviews](https://www.fda.gov/media/116168/download). Available at <https://www.fda.gov/media/116168/download>.

⁹ Pub. L. 105-115

¹⁰ Pub. L. 112-144

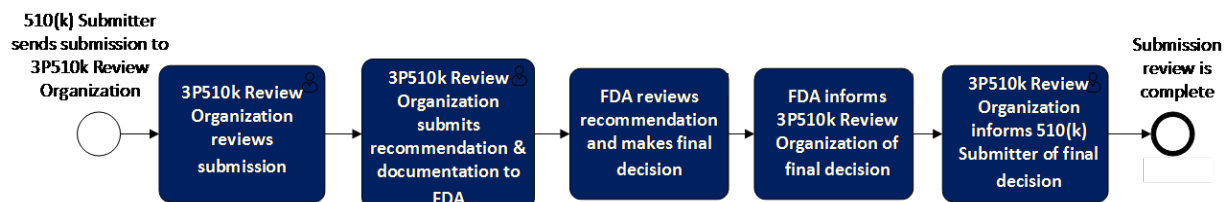
Contains Nonbinding Recommendations

On August 18, 2017, FDARA¹¹ was signed into law and required FDA to issue guidance on the factors FDA will use in determining whether a class I or class II device type, or subset of such device types, is eligible for review by 3P510k Review Organizations, including the risk of the device type and whether the device type is permanently implantable, life sustaining, or life supporting, and whether there is a detailed public health justification for permitting the review by an accredited person of such device type. This guidance also addresses several MDUFA IV commitments by including an early interaction consult policy and clarifying criteria for rerecognition of 3P510k Review Organizations and the suspension or withdrawal of recognition.¹²

B. General Overview of 3P510k Review Program

The 3P510k Review Program is intended to support CDRH's mission to protect and promote public health by enabling FDA to focus its internal scientific review resources on higher-risk and complex devices, while maintaining a high degree of confidence in the review of low-to-moderate risk and less complex devices by 3P510k Review Organizations, and to provide manufacturers of eligible devices a voluntary alternative review process that may yield more rapid decisions on 510(k)s. See section 523(a)(3) of the FD&C Act. Figure 1 below provides a schematic overview of the 3P510k Review Program.¹³

Figure 1 – A General Overview of the 3P510k Review Program



Under the 3P510k Review Program, 3P510k Review Organizations review a 510(k) submission and then forward their review, the 510(k) submission, and a recommendation (e.g., substantially equivalent (SE) or not substantially equivalent (NSE)) to FDA. FDA reviews the 3P510k Review Organization's memo and recommendation and makes a final decision on the submission. Section 523(a)(2) of the FD&C Act requires FDA to make a determination with respect to the initial classification within 30 calendar days¹⁴ after receiving a recommendation from a 3P510k Review Organization. The 510(k) Submitter pays the 3P510k Review Organization directly; no

¹¹ Pub. L. 115-52

¹² Through the MDUFA IV Commitment Letter, FDA commits to improving the 3P Review Program with a goal of eliminating routine re-review by FDA of 3P510k reviews: *See* 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at <https://www.fda.gov/media/102699/download>.

¹³ Figure 1 uses IEC/IEC 19510: Information technology – Object Management Group Business Process Model and Notation (2013).

¹⁴ FDA uses calendar days when measuring on-time performance of user-fee supported premarket medical device submission reviews. *See*, “MDUFA Performance Goals and Procedures, Fiscal Years 2018 through 2022” at <https://www.fda.gov/media/102699/download> for more information.

Contains Nonbinding Recommendations

user fee is due to FDA for the 510(k) reviewed by the 3P510k Review Organization.¹⁵ A general principle of the 3P510k Review Program is that the 3P510k Review Organization is the conduit for communication to and from the 510(k) Submitter and to and from the FDA. This ensures the 3P510k Review Organization is fully informed and that communications do not undermine their role.

A 3P510k Review Organization must be recognized by FDA under section 523(b) of the FD&C Act to be eligible to participate in the 3P510k Review Program. FDA recognizes 3P510k Review Organizations¹⁶ to review 510(k)s for certain device types eligible for the 3P510k Review Program.¹⁷

Participation by 510(k) Submitters in the 3P510k Review Program is entirely voluntary. Manufacturers who do not wish to use a 3P510k Review Organization may submit their 510(k)s directly to the FDA for review, through either the Traditional, Special, or Abbreviated Programs, as appropriate.^{18, 19, 20}

As described in this guidance, the 3P510k Review Program includes features designed to ensure a high level of quality in the review of 510(k)s by a 3P510k Review Organization and to minimize risks to public health. In evaluating a 3P510k Review Organization for recognition or rerecognition, FDA will consider the application, as outlined in Section VIII of this guidance, provided by a 3P510k Review Organization. In addition, FDA may consider past premarket review performance of the 3P510k Review Organization as described in Section VIII.B.²¹

III. Scope

This guidance outlines FDA's current thinking on key aspects of the 3P510k Review Program, including:

1. FDA's expectations for 3P510k Review Organization reviews of 510(k) submissions, including the policy for early interaction consults (see Section VI)
2. Factors used to establish device type eligibility in the 3P510k Review Program (see Section V)
3. Requirements and recommendations for recognition and rerecognition of 3P510k Review Organizations under the 3P510k Review Program (see Section VII)

¹⁵ See Section 738(a)(2)(B) of the FD&C Act.

¹⁶ For a current list of recognized 3P Review Organizations under the 3P Review Program, please visit FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/Accredit.cfm>.

¹⁷ For a current list of eligible devices for 3P review under the 3P Review Program, please visit FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm>

¹⁸ The guidance document describing the 510(k) Program is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k>.

¹⁹ The guidance document for the Abbreviated 510(k) Program is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program>.

²⁰ The guidance document for the Special 510(k) Program is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program>.

²¹ See section 523(b)(2) and section 523(b)(3) of the FD&C Act.

Contains Nonbinding Recommendations

4. Content and format of a 3P510k Review Organization's application for initial recognition and rerecognition (see Section VIII)
5. Process for suspension or withdrawal of recognition (see Section IX)
6. Leveraging the International Medical Device Regulators Forum's (IMDRF's) requirements for Regulatory Reviewers under the Good Regulatory Review Practices (GRRP) and the Medical Device Single Audit Program (MDSAP), as appropriate (see Section X)

Currently accredited 3P510k Review Organizations should submit their application materials for recognition in the manner described in Section VIII of this guidance within six months of the publication date of this guidance.

IV. Definitions

The definitions provided below explain the terms used by FDA in the context of this guidance. These terms are not intended to be applied in any context beyond this document and the 3P510k Review Program.

Device Type: A device type or category as set forth in a section of the Code of Federal Regulations, as well as a subset of such device type, such as that set forth in a product code.

510(k) Submitter: An entity or person that submits a 510(k) submission to a 3P510k Review Organization for the purposes of demonstrating substantial equivalence (SE) of that device to a legally marketed device that is not subject to premarket approval (PMA).

Final Reviewer: An individual within the 3P510k Review Organization who oversees the review of a 510(k) submission throughout the entire review process. The Final Reviewer is a regulatory reviewer who meets the criteria of an IMDRF Regulatory Reviewer (defined below) and who is responsible for ensuring that final recommendations regarding the device made by the Product Specialist (defined separately) are appropriately evaluated, organized, and documented before documents are sent to FDA. This individual has sufficient authority and competence within the 3P510k Review Organization to independently evaluate the quality and acceptability of the 3P510k review documentation. The Final Reviewer is a separate individual from the Product Specialist.

IMDRF: International Medical Device Regulators Forum

IMDRF MDSAP Document: IMDRF MDSAP WG/N3 FINAL: 2016 (Edition 2) – “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”²² produced by the International Medical Device Regulators Forum (IMDRF) intended to implement the concept of a Medical Device Single Audit Program (MDSAP).²³ This document provides criteria for audit programs that FDA believes 3P510k Review Organizations

²² IMDRF MDSAP Working Group N3 Final: 2016 (Edition 2): “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition” can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160324-requirements-auditing-orar.pdf>.

²³ See <https://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/>.

Contains Nonbinding Recommendations

should follow, where applicable, and to the extent such criteria are appropriate and consistent with the FD&C Act and other applicable laws and regulations.

IMDRF Medical Device Single Audit Program: An international program, established by IMDRF, specifying a standard set of requirements for the recognition of auditing organizations performing regulatory audits of medical device manufacturers and other related functions.

IMDRF Regulatory Reviewer: An individual meeting and fulfilling the competencies, commitments, training, and conduct described in IMDRF/GRRP WG/N40 FINAL:2017 – “Competence, Training, and Conduct Requirements for Regulatory Reviewers”²⁴ produced by the International Medical Device Regulators Forum (IMDRF). This is IMDRF’s Good Regulatory Review Practices (GRRP) document describing criteria “for individuals who perform regulatory reviews of medical devices for marketing authorization,” whether those individuals work for governmental regulatory authorities or Conformity Assessment Bodies (CABs)²⁵ that FDA believes 3P510k Review Organizations should follow, where applicable, and to the extent such criteria are appropriate and consistent with the FD&C Act and other applicable laws and regulations.

Product Specialist: An individual within the 3P510k Review Organization, who meets the criteria of an IMDRF Regulatory Reviewer (defined above), and is qualified to review and evaluate medical devices within specific device type(s), who may also be qualified for a specific technical or clinical specialization (e.g., biocompatibility and Ethylene Oxide (EtO) sterilization), based on their scientific background and competence. This individual is the primary reviewer responsible for leading the 3P510k Review Organization’s review team on a given 510(k) submission. The Product Specialist submits their recommendation and all related documentation to the Final Reviewer.

Recognition: The process of accrediting 3P510k Review Organizations under section 523 of the FD&C Act to review premarket notifications submitted under section 510(k) of the FD&C Act of certain eligible devices and make recommendations to FDA regarding the initial classification of such devices under section 513(f)(1) of the FD&C Act.

Rerecognition: The process of renewing the accreditation of 3P510k Review Organizations under section 523 of the FD&C Act for an additional three years.

Recognition Criteria: The applicable FD&C Act requirements, including the qualification requirements set forth in section 523(b)(3); FDA’s recommendations described in this guidance

²⁴ IMDRF/GRRP WG/N40 Final:2017: “Competence, Training, and Conduct Requirements for Regulatory Reviewers” can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf>.

²⁵ “*Conformity Assessment Body (CAB)*: A body other than a Regulatory Authority engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled (GHTF/SG1/N78:2012)”, IMDRF/GRRP WG/N40FINAL:2017, section 3.6.

Contains Nonbinding Recommendations

document, including those criteria contained in IMDRF MDSAP WG N3²⁶, (which include the International Organization for Standardization (ISO)/the International Electrotechnical Commission (IEC) 17021:2011 “Conformity assessment – Requirements for bodies providing audit and certification of management systems”, where appropriate and applicable) and IMDRF GRRP WG N40²⁷; and the criteria to accredit or deny accreditation announced in the Federal Register.²⁸

Recognition Denial: The process of denying an application for accreditation submitted by a potential 3P510k Review Organization.

Rerecognition Denial: The process of denying an application for reaccreditation submitted by a recognized 3P510k Review Organization.

Recognition Withdrawal: The process of withdrawing or suspending accreditation of a 3P510k Review Organization in accordance with section 523(b)(2) of the FD&C Act.

Safety Signal: A signal represents a new potentially causal association or a new aspect of a known association between a medical device and an adverse event or set of adverse events.²⁹

Technical Expert: An individual who provides specific knowledge or expertise. This individual may be an employee of a 3P510k Review Organization or may be external as described below in Sections VI.B and VII.D of this guidance, respectively.

Third Party (3P510k) Review Organization: An organization recognized by FDA to review 510(k) submissions for certain eligible devices as authorized by section 523 of the FD&C Act.

V. Factors Used in Determining Device Type Eligibility in the 3P510k Review Program

The factors FDA will consider in determining device type eligibility for the 3P510k Review Program are as follows:

1. The risk of the device type, or subset of such device type.³⁰ FDA generally classifies medical devices based on risks associated with the device type and whether general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of

²⁶ IMDRF MDSAP Working Group N3 Final: 2016 (Edition 2): “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”, previously cited, can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160324-requirements-auditing-orar.pdf>.

²⁷ IMDRF/GRRP WG/N40 Final:2017: “Competence, Training, and Conduct Requirements for Regulatory Reviewers”, previously cited, can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf>.

²⁸ 63 FR 28388 (May 22, 1998) is available at <https://www.gpo.gov/fdsys/pkg/FR-1998-05-22/pdf/98-13799.pdf>.

²⁹ See Signal Management Program in “Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health” at <https://www.fda.gov/media/112497/download>.

³⁰ See section 523(a)(3)(B)(i)(I) of the FD&C Act.

Contains Nonbinding Recommendations

the device or there is sufficient information to establish special controls to mitigate such risks and provide such assurance. Devices are classified into one of three regulatory classes: class I, class II, or class III.³¹ In accordance with the statute, class III devices are not eligible for 3P510k review.³²

2. Whether the device type, or subset of such device type, is intended to be permanently implanted in the human body, to sustain human life, or to support human life. Any 3P510k Review Organization seeking recognition for review of such device types must provide a detailed public health justification explaining why this device type should be eligible for 3P510k review³³ and how this will positively impact public health.
3. The extent to which the device type is well understood. For example, devices with novel technological characteristics, including some devices requiring complex special controls initially classified through the De Novo process may be ineligible for 3P510k review.³⁴
4. The extent to which necessary information to make a well-informed recommendation is available to 3P510k Review Organizations. If information materially relevant to evaluating a device type cannot be shared outside the agency (e.g., it is proprietary), the device type may be ineligible for 3P510k review.
5. The extent to which the review of the device type does not require multifaceted, interdisciplinary expertise. The following are examples of scenarios that would likely be ineligible for 3P510k review due to the need for such expertise:
 - a. the review of some kinds of clinical data or complex non-clinical data (e.g., computational modeling);
 - b. a need for consultation across different FDA organizational components, or in cross-modality topics (e.g., a multi-reader clinical study);
 - c. a combination product or device type either of which requires review from another Center in the Agency;³⁵
 - d. if a device type raises novel cross-labeling considerations, such as the potential for off-label use of drugs (e.g., injector needles or syringes). “Cross-labeled” products usually refer to any drug, device, or biological product packaged separately that, according to its proposed labeling, is for use only with another

³¹ For more information on the classification of medical devices, please visit FDA’s website at <https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification>.

³² See section 523(a)(3)(A)(i) of the FD&C Act.

³³ See section 523(a)(3)(B)(i)(II) of the FD&C Act.

³⁴ The guidance document describing the De Novo process is available on FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/de-novo-classification-process-evaluation-automatic-class-iii-designation>.

³⁵ For more information on combination products, please visit FDA’s website at <https://www.fda.gov/combination-products/about-combination-products/frequently-asked-questions-about-combination-products>.

Contains Nonbinding Recommendations

individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect.³⁶

However, if a device type contains simple clinical data such as sample clinical images or tests using banked specimens, it may be eligible for 3P510k review. Most in vitro diagnostic (IVD) devices are eligible for 3P510k review as they typically rely on simple clinical studies to demonstrate SE, provided that such devices also meet the other factors listed in this section.

6. The availability of postmarket data suggesting that the device type is the subject of safety signals. For example, if a device type is the subject of a safety communication, a high-risk recall (Class I)³⁷, or postmarket data that indicate a safety signal, this device type may be ineligible for 3P510k review.

For example, as of the date of issuance of this guidance, duodenoscopes have a safety signal associated with their reprocessing.³⁸ Because of this safety signal, FDA may remove duodenoscopes and accessories from eligibility for the 3P510k Review Program.

FDA will consider each of the above factors in determining device type eligibility for 3P510k review. Furthermore, if a device type is considered eligible for 3P510k review, but a proposed modification to the device type for a specific submission raises different concerns related to the factors listed above, that submission may be determined to be ineligible for 3P510k review.

The product code classification database³⁹ and FDA's list of devices eligible for 3P510k review⁴⁰ has been updated to reflect these eligibility factors to determine 3P510k eligibility for device types. If eligible device types are determined to be ineligible for 3P510k review, or ineligible ones are determined to be eligible for 3P510k review, FDA will change their status in the database and FDA's publicly-available list. FDA will periodically review new device types using the factors described above to determine whether they are appropriate for 3P510k review, and update the database and list accordingly.

³⁶ For more information on cross-labeling and diagnostic devices, see the guidance "[In Vitro Companion Diagnostic Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/vitro-companion-diagnostic-devices)" available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/vitro-companion-diagnostic-devices>.

³⁷ For information on classification of recalls, please visit FDA's website at <https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices>.

³⁸ Information on safety signals associated with duodenoscopes is available on FDA's website at <https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscope.s>

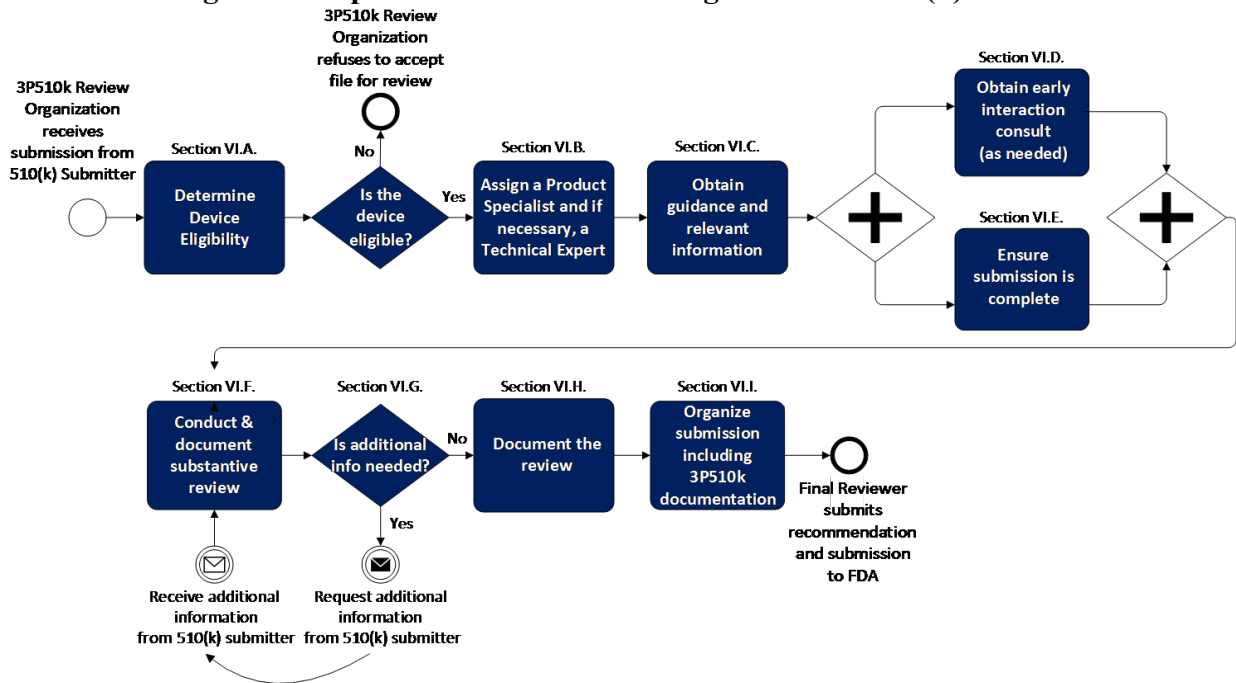
³⁹ The product code classification database is available on FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

⁴⁰ For a current list of eligible devices for 3P review under the 3P Review Program, please visit FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm>.

VI. Review of 510(k) Submissions by 3P510k Review Organizations

FDA believes that 3P510k Review Organizations should conduct FDA-equivalent reviews of eligible devices. 3P510k Review Organizations are responsible for reviewing and analyzing scientific and technical data in a 510(k) submission to make a recommendation regarding the device to the FDA. 3P510k Review Organizations should conduct their review of 510(k)s in the manner described in the sections below and in accordance with their own quality control practices. Figure 2 identifies the key steps in a 3P510k Review Organization’s review of a 510(k) submission.⁴¹

Figure 2: Steps in a 3P510k Review Organization’s 510(k) Review



A. Determine device eligibility for 3P510k review

Before reviewing a 510(k) submission, a 3P510k Review Organization should determine whether it has the expertise to review the device type and whether that device type is eligible for 3P510k review based on review of the product code classification database⁴² or the FDA Third Party Review public website.⁴³ If the 3P510k Review Organization lacks the expertise or the device is

⁴¹ Figure 2 uses IEC/IEC 19510: Information technology – Object Management Group Business Process Model and Notation (2013).

⁴² The product code classification database is available on FDA’s website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

⁴³ For a list of eligible devices for 3P review under the Third Party Review Program, please visit FDA’s website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm>.

Contains Nonbinding Recommendations

not eligible for 3P510k review, the 3P510k Review Organization should not accept the 510(k) for review from the 510(k) Submitter. If the 3P510k Review Organization determines the device is ineligible for 3P510k review after it has already accepted the 510(k) submission, the 3P510k Review Organization should immediately inform the 510(k) Submitter and discontinue the review.

If the 3P510k Review Organization submits a 510(k) submission to FDA for an ineligible device, or a device the 3P510k Review Organization is not recognized to review (see Section VIII.A), FDA will place the submission on hold and notify the 3P510k Review Organization of FDA's eligibility assessment. Unless the 3P510k organization intends to address the eligibility concerns, it should promptly consult with the 510(k) Submitter and, if the 510(k) Submitter concurs, promptly send a 510(k) withdrawal request to FDA. If the 3P510k Review Organization does not address eligibility concerns or withdraw the submission within 180 days, FDA will delete the file. A 510(k) Submitter cannot submit a 510(k) for the same device directly to FDA until the file is withdrawn voluntarily by the 3P510k Review Organization or deleted automatically by FDA after 180 days. If a 3P510k Review Organization is unclear regarding the eligibility status of a device, it should contact the 3P510k inbox at 3P510K@fda.hhs.gov to seek clarification.

B. Assign a Product Specialist(s) and Technical Expert(s) to conduct the substantive review of a 510(k) submission

3P510k Review Organization personnel should have appropriate education, training, skills, technical knowledge, qualifications, and experience to perform 510(k) reviews for the device type(s) their organization is recognized to review. For additional discussion on FDA's recommendations regarding qualifications of personnel, see Section VII.C of this guidance.

Each 510(k) submission should be assigned to a Product Specialist with appropriate expertise for the type of device under review. The Product Specialist may add qualified Technical Experts to the review team to ensure sufficient competency in the review, if necessary. The Product Specialist should document the competencies of, and the rationale for, choosing to use any Technical Experts. Particular attention should be given to the expertise and impartiality of any external Technical Experts. For more information on using external Technical Experts, please see Section VII.D of this guidance.

C. Obtain relevant FDA guidance(s) and information

3P510k Review Organizations should review and be familiar with publicly available information relevant to their review. For example:

1. 3P510k Review Organizations should review FDA's guidance database to obtain any relevant final guidance documents⁴⁴ when conducting their reviews, including device-specific and horizontal guidances (e.g., biocompatibility, software, sterility).

⁴⁴ The guidance database search engine allows users to search the inventory of guidances available by title, words, or origin and is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>

Contains Nonbinding Recommendations

In addition, 3P510k Review Organizations should be aware of any special controls, which are regulatory requirements for certain class II devices, that apply to that device type under review. For information on whether a device type has applicable special controls, 3P510k Review Organizations should review the proposed classification regulation of the device under Title 21 of the Code of Federal Regulations (CFR),⁴⁵ which will identify the mandatory special controls for a particular device type.

2. 3P510k Review Organizations should review FDA's postmarket databases, including recalls, market withdrawals, and safety reports;⁴⁶ Medical Device Reports;⁴⁷ and MedSun Reports⁴⁸ for the predicate device and/or the device type to identify any issues with clinical use of similar devices that should be considered and addressed in the review of the subject device. If potential safety signals are identified by a 3P510k Review Organization, it should contact FDA for information on current review practice (see Section VI.D below).
3. 3P510k Review Organizations should review publicly available premarket review information in FDA's 510(k) database for information about the legally marketed device ('predicate') to which a Submitter is comparing its device, or other similar devices,⁴⁹ including Indications for Use Statements, 510(k) Summaries,^{50,51} Decision Summaries (if available), and FDA decision letters. In some instances, a device's product code can also be used to identify a generic category of a device and assist with the identification of similar devices. Product codes can be found in FDA's product code database.⁵²

⁴⁵ The Code of Federal Regulations Title 21 database is available at <https://www.ecfr.gov/cgi-bin/ECFR?page=browse>

⁴⁶ The recalls database allows users to search for recalls and correction or removal actions initiated by a firm prior to recall classification and is available on FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>.

⁴⁷ The MAUDE database allows users to search for Medical Device Reports and is available on FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>.

⁴⁸ The MedSun database allows users to search for adverse event reports from the Medical Product Safety Network and is available on FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>.

⁴⁹ The 510(k) database search engine allows users to search all previously cleared 510(k) submissions by 510(k) number, applicant name, device name, product code, etc., and is available on FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>.

⁵⁰ 510(k) Summaries should be written in accordance with 21 CFR 807.92 and is available at https://www.ecfr.gov/cgi-bin/text-idx?SID=7272ad96195b5a401402c8b22c785d10&mc=true&node=se21.8.807_192&rgn=div8.

⁵¹ The guidance document describing 510(k) Summaries is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k>.

⁵² The product code database is available on FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

Contains Nonbinding Recommendations

4. If an applicant wishes to utilize standards, the 3P510k Review Organization should review FDA’s guidance document entitled “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#).”⁵³

3P510k Review Organizations should request that 510(k) Submitters fully inform them of any prior communications with FDA about a device under review, including but not limited to FDA feedback obtained through the Q-Submission program, unsuccessful marketing applications, and other interactions. If applicable, 3P510k Review Organizations should be familiar with the FDA Q-Submission Program, including the Pre-Submission process, through the guidance document entitled, “[Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program](#).”⁵⁴ A 3P510k Review Organization should request that the authorization letter from the 510(k) Submitter grant FDA permission to discuss previous submissions, identified by submission numbers, with the 3P510k Review Organization (see Section VI. I). If applicable, the 3P510k Review Organization should coordinate with the 510(k) Submitter to obtain and review prior submission content for the device, any written feedback or meeting minutes resulting from prior interactions, and any additional data, studies and/or study protocols submitted in response to previous submissions by the 510(k) Submitter prior to submitting the current submission to FDA.

3P510k Review Organizations should also request that 510(k) Submitters submit only one 510(k) for a specific device at a time.

D. Early Interaction with FDA (as needed)

3P510k Review Organizations should interact, as needed, with appropriate FDA staff prior to, and during the review of, 510(k) submissions. Early interactions – those between the 3P510k Review organization and FDA prior to the substantive review – can be an important part of the 510(k) review process (for potential topics, refer to section VI.C). These interactions help ensure timely and consistent 510(k) reviews by assisting in device eligibility determinations and identifying relevant issues and contemporary review criteria.

In their initial recognition applications, 3P510k Review Organizations commit to early interaction with FDA before reviewing a device type they have not previously reviewed (see Section VIII.A). This ensures the 3P510k Review Organization has the latest FDA thinking on relevant guidance, standards, and other considerations for that device type. FDA also encourages early interaction for all 3P510k submissions, particularly for the first review of any device type by an individual Product Specialist and for any subset of device type (i.e., device type by product code) they have not recently reviewed. Generally, FDA considers a recent review to be within the last six months.

⁵³ The guidance document describing the use of standards to determine substantial equivalence is available on FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

⁵⁴The guidance document describing the Q-Submission program is available on FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>.

Contains Nonbinding Recommendations

Procedures on how to obtain early interaction will be available on the FDA Third Party public website. FDA intends to respond to 3P510k Review Organization requests within 2 business days. If that deadline cannot be met, FDA will work with the 3P510k Review Organization to establish a reasonable timeline for a response.

E. Ensure a submission is administratively complete

To ensure that a submission is administratively complete, 3P510k Review Organizations should conduct an acceptance review of the 510(k) submission based on 510(k) regulations from 21 CFR 807.87 to 807.100 to assess whether the 510(k) submission includes all the information necessary to conduct a substantive review and to reach a recommendation (e.g., SE or NSE) as defined under section 513(i) of the FD&C Act to submit to FDA. FDA recommends that 3P510k Review Organizations use the Refuse to Accept (RTA) checklist for 510(k) submissions to make the determination regarding whether a submission is administratively complete. For more information on the RTA checklist, please see FDA's guidance document entitled "[Refuse to Accept Policy for 510\(k\)s](#)."⁵⁵

3P510k Review Organizations should not act as a consultant for the 510(k) Submitter. It is the responsibility of the 510(k) Submitter to be familiar with the content and format requirements of a 510(k) prior to submitting to a 3P510k Review Organization. If a Submitter is not familiar with the 510(k) regulatory pathway, 3P510k Review Organizations should direct them to resources such as FDA's guidance documents entitled, "[The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](#),"⁵⁶ "[The Abbreviated 510\(k\) Program](#),"⁵⁷ "[The Special 510\(k\) Program](#),"⁵⁸ or the Division of Industry and Consumer Education in the Office of Communication and Education.⁵⁹

If the 3P510k Review Organization determines that a submission is administratively complete, the organization should begin its substantive review of the 510(k) submission. If the 3P510k Review Organization identifies any deficiencies in the 510(k) submission, it should contact the 510(k) Submitter to request the missing information.

⁵⁵ The guidance document for Refuse to Accept policy is available on FDA's website at

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks>.

⁵⁶ The guidance document for the 510(k) Program is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k>.

⁵⁷ The guidance document for the Abbreviated 510(k) Program is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program>.

⁵⁸ The guidance document for the Special 510(k) Program is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program>.

⁵⁹ The contact information for the Division of Industry and Consumer Education is available on FDA's website at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>.

F. Conduct the substantive review of a 510(k) submission

Substantive review focuses on the evaluation of SE as defined in section 513(i) of the FD&C Act. 21 CFR 807.100(b) sets forth the criteria that FDA uses to determine whether a device is substantially equivalent to a legally marketed device. For information on making an SE determination under the 510(k) program, please see FDA’s guidance document entitled “[The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](#).”⁶⁰ For information on Abbreviated and Special 510(k)s, see FDA’s guidance documents entitled “[The Abbreviated 510\(k\) Program](#)”⁶¹ and “[The Special 510\(k\) Program](#).”⁶²

3P510k Review Organizations should identify at least one Final Reviewer within its organization who is independent from prior review of the submission and is responsible for providing a final supervisory assessment of the Product Specialist’s work before it is submitted to FDA. This individual should have sufficient authority and competence to independently assess the quality and acceptability of the Product Specialist’s review of the 510(k) submission.

If 3P510k Review Organizations identify any deficiencies during their substantive review, they should contact the 510(k) Submitter with a request that the deficiencies be addressed. Section VI.G below provides further instruction on how to identify deficiencies in a 510(k) submission. When the substantive review is complete, the Product Specialist(s), Technical Expert(s), if applicable, and Final Reviewer should reach an agreement on a final recommendation (e.g., SE or NSE to a predicate device) before submitting the recommendation to FDA.

G. Identify deficiencies in a 510(k) submission

If a 3P510k Review Organization identifies any deficiencies during their review, it should contact the 510(k) Submitter. 3P510k Review Organizations may use any form of communication (i.e., telephone, facsimile, electronic mail, or letter) to resolve the matter provided confidentiality is maintained and the interaction is documented. 3P510k Review Organizations should, however, avoid the exchange of substantive data and information solely over the telephone to avoid errors that may arise in the absence of a written request and response.

As part of providing an FDA-equivalent review, when requesting additional information from a 510(k) Submitter, 3P510k Review Organizations should structure their additional information requests as described in FDA’s guidance document entitled “Developing and Responding to

⁶⁰ The guidance document used to determine the substantial equivalence of a device is available on FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k>.

⁶¹ The guidance document for the Abbreviated 510(k) Program is available on FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program>.

⁶² The guidance document for the Special 510(k) Program is available on FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program>.

Contains Nonbinding Recommendations

Deficiencies in Accordance with Least Burdensome Provisions.”⁶³ This guidance document has examples of well-constructed deficiencies and responses to FDA’s requests.

3P510k Review Organizations should document the deficiencies, the 510(k) Submitter’s response to the deficiencies, and the discussion on the adequacy of the response in the 3P510k Review Organization’s review memorandum sent to FDA. The review memorandum should also provide to FDA a copy of all written communications related to resolving the deficiencies between the 510(k) Submitter and the 3P510k Review Organization (e.g., electronic mail, letters, summary of teleconferences). If the 510(k) Submitter made any modifications to the submission in response to a deficiency (e.g., revised 510(k) summary), the 3P510k Review Organization should document this modification and request that the 510(k) Submitter provide the latest version of the 510(k) submission prior to the 3P510k Review Organization submitting to FDA. For example, if the Product Specialist requested an updated device description, the latest version should be in the 510(k) submission to FDA. However, the original device description and the deficiency requesting an updated device description should be found in the review memo. This will ensure that FDA has the correct version of the 510(k) submission on record. Proper documentation will ensure that the 3P510k Review Organization does not have or appear to have the role of a consultant.

H. Document a 510(k) review

Once a 3P510k Review Organization has made a final recommendation, it should prepare their review documentation specifying the reasoning and steps that led to their final recommendation. 21 CFR 10.70 (“Documentation of significant decisions in administrative file”) provides a framework that should be utilized by 3P510k Review Organizations. The content of the review documentation will vary based on the type of 510(k) submission and device. Recommended review memorandum examples for documentation purposes will be available on the FDA Third Party public website.⁶⁴

If standards are referenced in a submission, FDA recommends 3P510k Review Organizations discuss in their review memorandum how they were utilized in the 510(k) submission. Submitters and 3P510k Review Organizations should consult the FDA guidance entitled, “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)”⁶⁵ for use of FDA-recognized consensus standards and use of other standards.

In addition to noting whether or not the necessary information required in a 510(k) submission was included,⁶⁶ the review memorandum should also convey how a 3P510k Review Organization made their recommendation regarding the device. A thorough and substantive

⁶³ The guidance document on developing and responding to deficiencies is available on FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-responding-deficiencies-accordance-least-burdensome-provisions>.

⁶⁴ Review examples will be available on FDA’s third party website: <https://www.fda.gov/medical-devices/premarket-submissions/510k-third-party-review-program>.

⁶⁵ The guidance on use of consensus standards is available on FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

⁶⁶ See 21 CFR 807 Subpart E.

Contains Nonbinding Recommendations

review memorandum should discuss the adequacy of each section of the submission. In general, FDA believes it will not be sufficient to state that a section of the 510(k) submission or a response to a deficiency was adequate without providing an explanation of how the 3P510k Review Organization came to that determination.

To facilitate FDA's review process, 3P510k Review Organizations should reference sections and page numbers of the 510(k) submission in their review memorandum where possible. 3P510k Review Organizations should also clearly document in the review memorandum any deficiencies, the response to the deficiencies, and the 3P510k Review Organization's review of the response as indicated in Section VI.G.

The review memorandum is the only means by which FDA can understand how and why a 3P510k Review Organization recommended a device to be SE (or NSE) to the predicate device. Thorough and clear documentation will reduce the need for FDA to re-review the submission itself and increase the efficiency of FDA's final review.⁶⁷

I. Organize and submit a 510(k) submission including associated 3P510k review documentation

Upon completing the review of a 510(k) submission, the Final Reviewer should submit two separate eCopy documents to FDA's Document Control Center,⁶⁸ the 510(k) submission generated by the 510(k) Submitter and the 3P510k review documentation generated by the 3P510k Review Organization.

Since there are two distinct parties involved in the generation of a 3P510k submission, the 3P510k Review Organization and the 510(k) Submitter, each is subject to the eCopy requirements and each must provide their own eCopy and company cover letter with an eCopy statement and signature (see section 745A(b) of the FD&C Act). The 510(k) Submitter should take care to submit the latest version of the 510(k) submission. This version should include any documents that have been updated in response to deficiencies from the 3P510k Review Organization. Please refer to FDA's guidance entitled "[eCopy Program for Medical Device Submissions](#)"⁶⁹ for more information on how to submit through the eCopy program.

⁶⁷ Through the MDUFA IV Commitment Letter, FDA commits to improving the 3P Review Program with a goal of eliminating routine re-review by FDA of 3P reviews: *See* 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at <https://www.fda.gov/media/102699/download>. *See also* "Eliminating Routine FDA Re-Review of Third Party 510(k) Reviews, available at <https://www.fda.gov/media/116168/download>.

⁶⁸ The address for CDRH's Document Control Center is available on FDA's website at <https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions>.

⁶⁹ The guidance document on eCopies is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions>.

Contains Nonbinding Recommendations

To facilitate FDA's review, we recommend that a 3P510k Review Organization's 510(k) documentation include the following:

- (1) A cover letter signed by the Final Reviewer that clearly identifies:
 - a. The purpose of the submission
 - b. The name and address of the 3P510k Review Organization and the contact person
 - c. The name, email address, and telephone number of the Final Reviewer
 - d. The name and address of the 510(k) Submitter
 - e. The name of the device (trade name, common or usual name, FDA classification regulation name, classification regulation number, and product code, as applicable)
 - f. The 3P510k Review Organization's recommendation (SE or NSE) with respect to the device
 - g. The date the 3P510k Review Organization first received the 510(k) from the Submitter
- (2) A letter signed by the 510(k) Submitter authorizing the 3P510k Review Organization to submit the 510(k) to FDA on their behalf and authorizing the 3P510k Review Organization to discuss the contents of the 510(k) with FDA on their behalf. This letter should also authorize FDA to discuss other, related submission(s) from the same 510(k) submitter with the 3P510k Review Organization and should include a list of those submission numbers.
- (3) A signed certification that the reported information accurately reflects the data reviewed and that no material fact has been omitted. This certification should also state that the 3P510k Review Organization continues to meet personnel qualifications and prevention of conflicts of interest criteria reviewed by FDA; that the 3P510k Review Organization's review is based on the 510(k) that it is submitting with the review; and that the 3P510k Review Organization understands that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).
- (4) A table of contents listing the sections where the 510(k) submission and associated 3P510k review documentation are located, along with the corresponding page numbers.
- (5) A summary of any early interaction consults that occurred prior to the 510(k) submission to FDA with FDA staff, if appropriate (see Section VI.D of this guidance).
- (6) The 510(k) Submitter's complete 510(k) submission that conforms to FDA's requirements for content and format as provided in 21 CFR part 807 subpart E. The 510(k) submission should be prepared by the 510(k) Submitter, not the 3P510k Review

Contains Nonbinding Recommendations

Organization. This information should be separate from the 3P510k Review Organization's documentation and should be the latest version. Please see Section VI.G for more information. Proper documentation will ensure that the 3P510k Review Organization does not have or appear to have the role of a consultant.

- (7) An acceptance review of the 510(k) submission based on objective criteria using the RTA checklist, discussed in Section VI.E of this guidance, to assess whether the submission is administratively complete and includes all of the information necessary for the 3P510k Review Organization to conduct a substantive review on FDA's behalf.
- (8) A review memorandum including complete documentation of the 3P510k Review Organization's review of the 510(k) submission as described in Sections VI.G and VI.H of this guidance, signed by all personnel who conducted the review (generally the Product Specialist(s), Technical Expert(s), when applicable, and Final Reviewer), with a decision recommendation.

FDA will begin its review of the 3P510k Review Organization's recommendation only after it receives all documentation it believes is needed to conduct its review.

J. Submit additional information upon FDA's request

After a 3P510k Review Organization has submitted their 510(k) recommendation, including the associated 3P510k review documentation, FDA will begin to review the 3P510k review documentation, and if necessary, the 510(k) submission. If FDA determines that additional information is needed to make an SE determination, it will contact the 3P510k Review Organization either by telephone or email.⁷⁰ Such requests will describe FDA's concerns with a 510(k) submission, and identify the information needed to address those concerns.

If FDA places a 510(k) submission "on hold" (i.e., officially suspends review of the submission pending FDA's receipt of additional information), it will send an email informing the 3P510k Review Organization of the "on hold" status and request additional information. For more information on a request for additional information, please see FDA's guidance entitled "[FDA and Industry Actions on Premarket Notification \(510\(k\)\) Submissions: Effect on FDA Review Clock and Goals](#)."⁷¹

Upon receiving a request from FDA for additional information, the 3P510k Review Organization should:

⁷⁰ Through the MDUFA IV Commitment Letter, FDA commits to improving the 3P Review Program with a goal of eliminating routine re-review by FDA of 3P reviews: *See* 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at <https://www.fda.gov/media/102699/download>.

⁷¹ The guidance document on FDA review clocks is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals>.

Contains Nonbinding Recommendations

- (1) Promptly inform the 510(k) Submitter of FDA’s request for additional information relating to the 510(k) submission and request that the 510(k) Submitter provide responses to the 3P510k Review Organization in writing.

The 3P510k Review Organization should be involved in any discussions with FDA regarding the request for additional information, such as if the 510(k) Submitter seeks clarification or a Submission Issue Meeting⁷² with FDA;

- (2) Thoroughly review any additional information provided by the 510(k) Submitter to ensure that it adequately responds to FDA’s concerns;
- (3) Document their review of the response to the deficiency by providing a clear and thorough assessment of whether and how the response adequately addresses FDA’s deficiency – this should include updating the review documentation accordingly;
- (4) Prepare a cover letter referencing the 510(k) number previously assigned by FDA and identifying the purpose of the new submission (i.e., response to deficiencies);
- (5) Send the cover letter, their additional or revised review documentation, and any additional information received from the 510(k) Submitter to FDA’s Document Control Center.⁷³

The 3P510k Review Organization must provide the two separate eCopy documents⁷⁴ (the new submission eCopy document generated by the 510(k) Submitter and the eCopy document generated by the 3P510k Review Organization). Each eCopy should be clearly marked as belonging to the 3P510k Review Organization or the 510(k) Submitter as appropriate. For information on the eCopy program, see Section VI.I of this guidance.

FDA will begin its review after it receives the 510(k) Submitter’s response to the additional information request, documentation of the 3P510k Review Organization’s review, and the 3P510k Review Organization’s determination of the adequacy of the response to additional information requests.

K. 510(k) submission dispute resolution

FDA has developed guidance documents that provide an overview of the appeals processes available for medical devices (see FDA’s guidances entitled “[Center for Devices and](#)

⁷² Submission Issue Meetings are discussed in the guidance document on the Q-Submission program, available on FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>.

⁷³ The address for CDRH’s Document Control Center is available on FDA’s website on the page describing the eCopy program at <https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions>.

⁷⁴ The guidance document describing the eCopy Program is available on the FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions>.

Contains Nonbinding Recommendations

[Radiological Health Appeals Processes](#)⁷⁵ and “[Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A](#)”⁷⁶). The processes for reviewing and reconsidering FDA decisions or actions on other 510(k) submissions are also available for 3P510k submissions when a dispute between FDA and a 510(k) Submitter arises.

Disputes are often the result of misunderstanding or miscommunication, and FDA encourages 3P510k Review Organizations to seek clarification, as needed, from FDA or the 510(k) Submitter during a review. If the 510(k) Submitter disagrees with an FDA decision or action, the 3P510k Review Organization should maintain impartiality and exercise care to avoid the appearance of conflict of interest that may result from acting as an advocate on the 510(k) Submitter’s behalf.

If a 510(k) Submitter would like to issue a complaint against a 3P510k Review Organization, communication should be sent to 3P510K@fda.hhs.gov.

VII. Requirements and Recommendations for Recognition and Rerecognition of Third Party Review Organizations

In this section of the guidance, FDA describes the criteria considered in recognizing 3P510k Review Organizations to conduct premarket reviews of eligible 510(k)s as established by FDASIA.

In accordance with section 523(b)(3) of the FD&C Act, a 3P510k Review Organization shall, at a minimum, meet the following qualification requirements. Such person:

- (1) May not be an employee of the Federal Government
- (2) Shall be an independent organization, which is not owned or controlled by a manufacturer, supplier, or vendor of devices, and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.
- (3) Shall be a legally constituted entity permitted to conduct the activities for which it seeks recognition
- (4) Shall not engage in the design, manufacture, promotion, or sale of devices
- (5) The operations of such person shall be in accordance with generally accepted professional and ethical business practices

⁷⁵ The guidance document describing the CDRH appeals process is available on FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes>.

⁷⁶ The guidance document on the CDRH appeals process, specifically regarding 517A is available on FDA’s website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a>.

Contains Nonbinding Recommendations

- (6) Shall agree, at a minimum, to include in its request for accreditation a commitment to, at the time of accreditation, and at any time it is performing any review pursuant to section 523:
- a. Certify that reported information accurately reflects data reviewed
 - b. Limit work to that for which competence and capacity are available
 - c. Treat information received, records, reports, and recommendations as proprietary information
 - d. Promptly respond and attempt to resolve complaints regarding its activities for which it is recognized
 - e. Protect against the use, in carrying out the review of a 510(k) submission and initial classification of a device, of any officer or employee of the person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the 3P510k Review Organization, and the officers and employees of the 3P510k Review Organization, have maintained compliance with requirements relating to financial conflicts of interest

In addition to these minimum requirements set forth in the FD&C Act, a 3P510k Review Organization should meet additional qualifications announced in the Federal Register.⁷⁷ These qualifications include establishing policies designed to identify, prevent, and ensure reporting to FDA, of instances where 510(k) Submitters submit substantially the same submission to multiple 3P510k Review Organizations in order to find the one most likely to recommend a substantial equivalence (SE) determination of the 510(k). Such a practice would undermine the independence and integrity of the 3P510k Review Program.⁷⁸ Other qualifications listed in the Federal Register or that have been previously identified through guidance are discussed below.

A. Operational considerations

All submissions and communications with FDA and all documentation pertaining to the review of a 510(k) submitted to FDA should be in English. For foreign 3P510k Review Organizations, a United States representative should be designated so that FDA can efficiently communicate with the 3P510k Review Organization while conducting its review (see Section VIII.A(1)).

B. Management of impartiality

FDA expects 3P510k Review Organizations to be impartial and free from any commercial, financial, and other pressures that might present a conflict of interest or an appearance of a conflict of interest. Therefore, FDA will consider whether the potential 3P510k Review

⁷⁷ 63 FR 28388 (May 22, 1998) is available at <https://www.gpo.gov/fdsys/pkg/FR-1998-05-22/pdf/98-13799.pdf>

⁷⁸ As noted in 63 FR 28390 (May 22, 1998), available at <https://www.gpo.gov/fdsys/pkg/FR-1998-05-22/pdf/98-13799.pdf>.

Contains Nonbinding Recommendations

Organization has established, documented, and executed policies and procedures to prevent any individual or organizational conflict of interest or the appearance of a conflict of interest, including conflicts of interests pertaining to their external Technical Experts. Policies and procedures intended to address this issue should be consistent with IMDRF MDSAP WG/N3 FINAL: 2016 (Edition 2) – “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”⁷⁹ and IMDRF GRRP WG/N40 FINAL:2017 – “Competence, Training, and Conduct Requirements for Regulatory Reviewers.”⁸⁰ For more information on IMDRF GRRP and MDSAP, see Section X of this guidance below.

FDA recommends that 3P510k Review Organizations also address the following to prevent a potential conflict of interest:

- (1) 3P510k Review Organizations should not participate in the preparation of 510(k)s if involved in 510(k) reviews. For more information, see Section VI.E of the guidance.
- (2) 3P510k Review Organizations should not task an individual, whether employee or contractor, with reviewing a 510(k) submission, if that individual was employed within the last twelve months by that 510(k) Submitter or by a firm who helped prepare that 510(k) submission. Personnel should not review a medical device that they developed, helped develop, or prepared for submission.
- (3) 3P510k Review Organizations should not promise or advertise any guarantees for FDA clearance.

Information on the conflict of interest standards FDA applies to its own review personnel is included in the document entitled “Standards of Ethical Conduct for Employees of the Executive Branch.”⁸¹ 3P510k Review Organizations are encouraged to refer to these standards in safeguarding their operations against conflicts of interest.

The conflict of interest policies for a 3P510k Review Organization should be fully implemented and there should be an attestation that those policies have been implemented that is signed by the most responsible individual at the organization before any 510(k) is accepted for review. When using external technical experts, see Section VII.D regarding conflicts of interest safeguards.

⁷⁹ IMDRF MDSAP Working Group N3 Final: 2016 (Edition 2): “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”, previously cited, can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160324-requirements-auditing-orar.pdf>.

⁸⁰IMDRF GRRP WG/N40 Final:2017: "Competence, Training, and Conduct Requirements for Regulatory Reviewers", previously cited, can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf>.

⁸¹ Standards of Ethical Conduct for Employees of the Executive Branch is available at: [https://www.oge.gov/Web/oge.nsf/0/076ABBBFC3B026A785257F14006929A2/\\$FILE/SOC%20as%20of%2081%20FR%2081641%20FINAL.pdf](https://www.oge.gov/Web/oge.nsf/0/076ABBBFC3B026A785257F14006929A2/$FILE/SOC%20as%20of%2081%20FR%2081641%20FINAL.pdf).

C. Personnel involved in reviewing activities⁸²

FDA expects that 3P510k Review Organizations and their personnel should demonstrate knowledge and experience with the following, as applicable:

- (1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
- (2) The Public Health Service Act (42 U.S.C. 201 et seq.)
- (3) Regulations in the Code of Federal Regulations implementing these statutes, particularly 21 CFR Parts 800 through 1299.

Additionally, the 3P510k Review Organization should:

- (4) Establish, document, and execute policies and procedures to ensure that 510(k)s are reviewed by qualified personnel.
- (5) Maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the technical review of a 510(k).
- (6) Make available to its personnel clear written instructions for duties and responsibilities with respect to 510(k) reviews.
- (7) Employ personnel who are qualified in all the scientific disciplines relevant to the 510(k)s that the 3P510k Review Organization accepts for review.
- (8) Identify at least one individual who is responsible for providing supervision over 510(k) reviews and who has sufficient authority and competence to assess the quality and acceptability of these reviews.

In addressing the items enumerated above in this section, 3P510k Review Organizations should be consistent with IMDRF MDSAP WG/N3 FINAL: 2016 (Edition 2) – “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”⁸³, including, but not limited to, maintaining a quality management system, and IMDRF GRRP WG/N40 FINAL:2017: "Competence, Training, and Conduct Requirements for Regulatory Reviewers".⁸⁴ For more information on IMDRF GRRP and MDSAP, see Section X of this guidance below.

⁸² Additional information on the criteria for personnel qualifications is available in the Federal Register notice published on 63 FR 28388 (May 22, 1998) at <https://www.gpo.gov/fdsys/pkg/FR-1998-05-22/pdf/98-13799.pdf>.

⁸³ IMDRF MDSAP Working Group N3 Final: 2016 (Edition 2): “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”, previously cited, can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160324-requirements-auditing-orar.pdf>.

⁸⁴ IMDRF GRRP WG/N40 FINAL:2017: "Competence, Training, and Conduct Requirements for Regulatory Reviewers", previously cited, can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf>.

Contains Nonbinding Recommendations

In addition, 3P510k Review Organizations will be expected to consult national and/or international standards recognized by FDA as well as FDA guidance documents. 3P510k Review Organizations should have the capability to interface with FDA's electronic data systems and websites through which the 3P510k Review Organization can search for relevant guidance documents, recognized standards, predicate summaries, and publicly available information regarding adverse events and recalls when performing premarket review of similar devices.

3P510k Review Organizations must certify in their application that designated personnel will attend FDA's training for recognition and rerecognition (see Section VIII.A of this guidance and the Federal Register notice published on May 22, 1998 (63 FR 28388)). 3P510k Review Organizations are expected to complete training before conducting any 510(k) reviews under the program. FDA will not accept 510(k) reviews and recommendations from 3P510k Review Organizations that have failed to have at least one designated person attend a FDA training session for recognition.

3P510k Review Organizations should be prepared to conduct technically competent 510(k) reviews before requesting recognition by FDA. FDA recommends persons involved in a 510(k) submission review at a 3P510k Review Organization meet the appropriate qualifications (e.g., specialized education and experience) provided in this guidance. When a 3P510k Review Organization requests to expand the scope of device types for which it may review 510(k) submissions, it should ensure through its policies and procedures in place that its staff are qualified in the scientific disciplines for the new device types.

D. Use of external Technical Experts

The following are FDA's recommendations when 3P510k Review Organizations use an external Technical Expert:

- (1) The 3P510k Review Organization should ensure that external Technical Experts meet the same standards as those who work within the 3P510k Review Organization, such as freedom from conflicts of interest;
- (2) The 3P510k Review Organization should ensure that external Technical Experts are discouraged from subcontracting parts of their contract to subcontractors, and if they do so, then the external Technical Expert should ensure that the subcontractor meets all requirements applicable to the external Technical Expert.;
- (3) 3P510k Review Organizations should maintain records of the qualifications of external Technical Experts, in addition to evidence of regular monitoring of the established competence, conflicts of interest and the degree of fulfillment of the outsourced work

To ensure that 3P510k Review Organizations have sufficient competence among their own staff, there should be at least one qualified Product Specialist per device type that the 3P510k Review Organization is recognized to review. This is to ensure that there is not excessive reliance on

Contains Nonbinding Recommendations

external expertise by a 3P510k Review Organization and to enable appropriate oversight of the qualifications of external Technical Experts by 3P510k Review Organizations.

In addressing the items above, 3P510k Review Organizations should be consistent with IMDRF MDSAP WG/N3 FINAL: 2016 (Edition 2): “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”⁸⁵ and IMDRF GRRP WG/N40 FINAL:2017: "Competence, Training, and Conduct Requirements for Regulatory Reviewers".⁸⁶ For more information on IMDRF GRRP and MDSAP, see Section X of this guidance below.

E. Confidential information

A 3P510k Review Organization is required to treat information received, records, reports, and recommendations as proprietary information (see section 523(b)(3)(F)(iii) of the FD&C Act) and may not disclose confidential commercial information or any trade secret (see section 301(y)(2) of the FD&C Act). Also, in accordance with 21 CFR 807.95, when a 510(k) is submitted by a device manufacturer to FDA, FDA will not publicly disclose that submission if certain conditions are met. Thus, a 3P510k Review Organization should not publicly disclose a 510(k) submission for a device that is not currently on the market and where the intent to market the device has not been disclosed.

FDA will determine whether information submitted to FDA by a 3P510k Review Organization can be released in accordance with the Trade Secrets Act, Freedom of Information Act, 21 CFR part 20 and 21 CFR 807.95, regarding confidentiality of information in 510(k)s. In general, as with 510(k)s submitted directly to FDA, 510(k)s submitted by 3P510k Review Organizations and associated review documentation will be available for disclosure by FDA after the agency has issued an SE decision for a device, unless the information is exempt from public disclosure under 21 CFR part 20 or 21 CFR 807.95. If necessary, a copy of the 510(k) will be provided to the manufacturer for predisclosure notification according to § 20.61.

In addition, information submitted by a 3P510k Review Organization to obtain recognition or rerecognition from FDA will be available for disclosure, unless exempted under 21 CFR part 20.

F. Complaints regarding 510(k) Submitters

The 3P510k Review Organization should send to FDA via e-mail to 3P510K@fda.hhs.gov information on any complaint (e.g., whistleblowing) it receives about a 510(k) Submitter that could indicate an issue related to the safety or effectiveness of a medical device or a public health risk.

⁸⁵ IMDRF MDSAP Working Group N3 Final: 2016 (Edition 2): “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition” can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160324-requirements-auditing-orar.pdf>.

⁸⁶ IMDRF GRRP WG/N40 FINAL:2017: "Competence, Training, and Conduct Requirements for Regulatory Reviewers", previously cited, can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf>.

G. Third Party Review Organization recordkeeping

Pursuant to section 704(f) of the FD&C Act, a 3P510k Review Organization must maintain records that support their initial and continuing qualifications to receive FDA recognition. These records must include the following:

- (1) Documentation of the training and qualifications of the 3P510k Review Organization and its personnel;
- (2) The procedures used by the 3P510k Review Organization for handling confidential information;
- (3) The compensation arrangements made by the 3P510k Review Organization; and
- (4) The procedures used by the 3P510k Review Organization to identify and avoid conflicts of interest.

In addition to these recordkeeping requirements, FDA recommends that 3P510k Review Organizations retain the following records for at least three years (3) following the submission of a 510(k) for review to FDA:

- (1) Copies of all 510(k) reviews and associated correspondence;
- (2) Information on the identity and qualifications of all personnel who contributed to the technical review of each 510(k); and
- (3) Other relevant records.

In addressing the items enumerated above, 3P510k Review Organizations should be consistent with IMDRF MDSAP WG/N3 FINAL: 2016 (Edition 2): “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”⁸⁷, including, but not limited to, records consistent with their quality management system, and IMDRF GRRP WG/N40 FINAL:2017: “Competence, Training, and Conduct Requirements for Regulatory Reviewers.”⁸⁸ For more information on the IMDRF documents, see Section X of this guidance.

In accordance with section 704(f)(1) of the FD&C Act, 3P510k Review Organizations must make the records specified in that section available upon request by an officer or employee of FDA. 3P510k Review Organizations shall permit the FDA officer or employee at all reasonable times to have access to, copy, and/or verify these records. Within 15 days of receipt of a written

⁸⁷ IMDRF MDSAP Working Group N3 Final: 2016 (Edition 2): “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”, previously cited, can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160324-requirements-auditing-orar.pdf>.

⁸⁸ IMDRF GRRP WG/N40 FINAL:2017: "Competence, Training, and Conduct Requirements for Regulatory Reviewers", previously cited, can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf>.

Contains Nonbinding Recommendations

request from FDA, 3P510k Review Organizations must make copies of the requested records available at the place FDA designates (see section 704(f)(2) of the FD&C Act). If FDA's monitoring of the 3P510k Review Program, such as a review of compensation arrangements between 3P510k Review Organizations and 510(k) Submitters, reveals that 510(k) Submitters are developing business relationships with 3P510k Review Organizations that call into question the independence or objectivity of a 3P510k Review Organization, FDA will consider limiting a Submitter's choice of 3P510k Review Organizations. Business relationships that may undermine the independence or objectivity of a 3P510k Review Organization include, for example, contracts between a manufacturer and a 3P510k Review Organization that represent a significant share of the 3P510k Review Organization's income.

Section 523(b)(3)(F)(iv) requires 3P510k Review Organizations to agree that they will promptly respond and attempt to resolve complaints regarding its activities for which it is accredited. FDA recommends that 3P510k Review Organizations establish a recordkeeping system for tracking the submission of those complaints and how those complaints were resolved, or attempted to be resolved.

VIII. Content and Format of an Application for Initial Recognition and Rerecognition as a 3P510k Review Organization

This section of the guidance provides FDA's recommendations on what should be included in an application to FDA for recognition as a 3P510k Review Organization.

The 3P510k Review Organization should inform FDA promptly if they would like to suspend, withdraw, cancel or reduce the scope of their program. FDA will adjust recognition or rerecognition as appropriate.

A. Initial Recognition

Organizations that wish to become recognized as 3P510k Review Organizations under section 523 of the FD&C Act should send their applications to FDA at the following address. To facilitate review of the application, FDA strongly encourages submission of an eCopy.⁸⁹

CDRH Third Party Premarket Review Program
U.S. Food and Drug Administration
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue,
Silver Spring, Maryland 20993 USA.
3P510K@fda.hhs.gov

⁸⁹ For information on the eCopy program, please see FDA's guidance entitled "[eCopy Program for Medical Device Submissions](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions)" available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions>.

Contains Nonbinding Recommendations

FDA will acknowledge receipt with an email to the applicant's designated contact person when the application is received. FDA will review these materials and respond within 60 calendar days⁹⁰ of the date of the receipt of the application with a decision to recognize or deny recognition, or a request for additional information. FDA may deem the application incomplete and deny recognition if the applicant fails to respond to FDA's request for additional information in a timely manner.

To facilitate review, the following information should be submitted in an application for FDA's consideration:

(1) Administrative information

- a. The name and mailing address of the 3P510k Review Organization seeking recognition;
- b. The telephone number, email address, and fax number of the contact person. The contact person should be the person to whom questions about the content of the application may be addressed and the person to whom a letter of determination and general correspondence will be directed. Foreign organizations should also identify the name, address, telephone number, email address, and fax number of an authorized representative located within the United States that will serve as the 3P510k Review Organization's contact with FDA (see also Section VII.A of this guidance);
- c. The name and title of the most responsible individual at the 3P510k Review Organization;
- d. A brief description of the 3P510k Review Organization, including: type of organization (e.g., not-for-profit institution, commercial business, other type of organization); size of organization (number of employees); number of years in operation; nature of work (e.g., testing or certification laboratory); and information regarding ownership (i.e., name of owner(s) and extent of ownership), operation, control of organization, and other related information sufficient for FDA to assess its degree of independence from entities such as device manufacturers and distributors;
- e. A listing of any national, state, local, or other recognition; and
- f. A list of the device types the applicant seeks to review by product codes or classification regulation name and regulation. Please refer to the FDA Third Party public website⁹¹ for devices that are eligible for 3P510k review.

⁹⁰ FDA uses calendar days when measuring on-time performance of user-fee supported premarket medical device submission reviews. See, "MDUFA Performance Goals and Procedures, Fiscal Years 2018 through 2022" available on FDA's website at <https://www.fda.gov/media/102699/download> for more information.

⁹¹ Information on third party eligible device types is available on FDA's website: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm>.

Contains Nonbinding Recommendations

(2) Prevention of conflicts of interest

A copy of the written policies and procedures established by the 3P510k Review Organization to ensure that the 3P510k Review Organization and its employees, external Technical Experts, contractors and individual contract employees involved in the evaluation of 510(k)s are free from conflicts of interest, and to prevent any individual or organizational conflict of interest, or appearance of conflict of interest that might affect the review process.

(3) Personnel qualifications

A list of personnel who will be involved in the preparation of the 3P510k Review Organization's 510(k) recommendations, including Product Specialists, Technical Experts, external Technical Experts, and Final Reviewers. Applicants should demonstrate that these personnel are technically competent to conduct 510(k) reviews and should document the following in their application:

- a. The written policies and procedures established to ensure 510(k)s are reviewed by qualified personnel;
- b. The written instructions for the duties and responsibilities of personnel with respect to 510(k) reviews;
- c. The written personnel standards established to ensure that designated personnel are qualified in all of the scientific disciplines presented by the 510(k)s for devices for which the 3P510k Review Organization is applying for its review;
- d. The documentation (e.g., curricula vitae or CVs) to establish that the reviewers of 510(k)s (i.e., Product Specialists and Technical Experts) and other involved non-supervisory personnel meet the Recognition Criteria for qualified personnel. This includes documentation of education, training, skills, abilities, and experience, including specialized education and experience needed for the review of devices for which the 3P510k Review Organization is applying for its review;
- e. The documentation (e.g., CVs) to establish that the supervisor(s) of 510(k) reviewers (i.e., Final Reviewer) have sufficient authority and meet the Recognition Criteria for qualified supervisory personnel. This includes documentation of education, training, skills, abilities, and experience, including specialized education and experience needed for the review of class II devices for which the 3P510k Review Organization is applying for its review; and
- f. A description of the management structure, or, if an external technical expert is used for 510(k) reviews, the external Technical Expert's management structure. The application should describe the position of the individual(s) providing supervision within the management structure and explain how that structure provides for the supervision of 510(k) reviewers and other personnel involved in the review process.

Contains Nonbinding Recommendations

(4) Certification statements

As required by statute, and to support FDA's plan to eliminate routine re-review of 3P510k submissions,⁹² the applicant must provide a statement in their application, signed by the most responsible individual at the organization, certifying that the 3P510k Review Organization has committed at the time of accreditation and at any time it is performing any 3P510k review that it:

- a. Will report information that accurately reflects data reviewed;
- b. Will limit work and reviews to that for which competence and capacity are available, including conducting 510(k) reviews in accordance with the policies and procedures it has established regarding review of 510(k)s by qualified personnel;
- c. Will treat any information, records, reports, and recommendations that they may receive as proprietary and confidential information;
- d. Will promptly respond and attempt to resolve complaints regarding the activities for which it is recognized;
- e. Will protect against conflicts of interests in accordance with policies and procedures it has established relating to prevention of financial conflicts of interests, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements relating to financial conflicts of interest;

FDA also encourages the applicant to certify in its application that at all times, it:

- a. Will demonstrate conformity while recognized by FDA with the requirements of section 523 of the FD&C Act;
- b. Will maintain records in a manner consistent with Section VII.G of this guidance;
- c. Will comply with the eCopy requirements⁹³ for premarket submissions as described in the guidance document entitled, "[eCopy Program for Medical Device Submissions](#)," as discussed in Section VI.I of this guidance;
- d. Commits that their most responsible person or designee(s) will have completed FDA training prior to performing any reviews by the 3P510k Review Organization, and agrees that their most responsible person or designee(s) will attend such training when offered and applicable;

⁹² See "Eliminating Routine FDA Re-Review of Third Party 510(k) Reviews", available on FDA's website at <https://www.fda.gov/media/116168/download>.

⁹³ See section 745A(b) of the FD&C Act.

Contains Nonbinding Recommendations

- e. Will contact FDA for early interaction before reviewing any subset of device type (by respective product code) that they have not reviewed as encouraged in Section VI.D of this guidance; and
- f. Will commit to only accepting reviews where the 510(k) Submitters certified that any relevant prior communications with FDA are disclosed.

B. Rerecognition

In accordance with section 523(b)(2)(D) of the FD&C Act, a 3P510k Review Organization's recognition by FDA will sunset 3 years from the date the recognition was granted under section 523 of the FD&C Act. To continue conducting 3P510k reviews beyond 3 years from the date of the last recognition or rerecognition, the 3P510k Review Organization must obtain rerecognition.

Requests for rerecognition will be handled in the same manner as initial recognition requests. Accordingly, rerecognition applications should follow the format described in Section VIII.A of this guidance. For rerecognition, FDA may also consider the past premarket review performance of the 3P510k Review Organization and any information that comes to FDA's attention about the status of the 3P510k Review Organization's recognition, including information from an audit.⁹⁴

FDA recommends that 3P510k Review Organizations apply for rerecognition a minimum of 60 calendar days before their recognition status expires to prevent any lapse in recognition. A 3P510k Review Organization may request a rerecognition earlier if it so chooses.

C. Recognition or Rerecognition Denial

A 3P510k Review Organization that wishes to request a reconsideration of a recognition denial or rerecognition denial may make a written request to FDA. For information about the appeals processes, please see FDA's guidance entitled "[Center for Devices and Radiological Health Appeals Processes](#)."⁹⁵ A written appeal should be submitted to the CDRH Ombudsman at:

CDRH Ombudsman
Center for Devices and Radiological Health
Food and Drug Administration
WO32 Room 4282
10903 New Hampshire Avenue
Silver Spring, Maryland 20993 USA

⁹⁴ See section 523(b)(2)(C) of the FD&C Act.

⁹⁵ Information on the appeals process for CDRH is available on FDA's website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes> and <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517>.

IX. Suspension or Recognition Withdrawal

Section 523(b)(2)(B) of the FD&C Act authorizes FDA to suspend or withdraw recognition of any 3P510k Review Organization, after providing notice and an opportunity for an informal hearing, when the 3P510k Review Organization is substantially not in compliance with the requirements of section 523 of the FD&C Act, poses a threat to public health or fails to act in a manner that is consistent with the purposes of section 523 of the FD&C Act.

Under section 301(y)(1) of the FD&C Act, the following actions are prohibited by a 3P510k Review Organization:

- (1) Submission of a report or recommendation that is false or misleading in any material respect;
- (2) Disclosure of confidential information or any trade secrets without the express written consent of the person who submitted such information or secrets to the 3P510k Review Organization; and
- (3) Receipt of a bribe in any form or doing any corrupt act associated with a responsibility delegated to the 3P510k Review Organization under the FD&C Act.

FDA will perform an assessment of each 3P510k Review Organization on a periodic (at least once every three years)⁹⁶ or “for cause” basis as part of its auditing to ensure 3P510k Review Organizations continue to meet the standards of recognition (see section 523(b)(2)(C) of the FD&C Act). Generally, as resources allow, assessments will involve inspecting a 3P510k Review Organization’s facility and/or records to ensure that the 3P510k Review Organization is operating in accordance with the procedures, qualifications, and certifications specified in the 3P510k Review Organization’s application and the FD&C Act.

Furthermore, FDA will periodically evaluate completed premarket reviews of 510(k)s submitted to FDA under the 3P510k Review Program and will provide feedback to Product Specialists and the Final Reviewer of 3P510k Review Organizations following its audits.

3P510k Review Organizations should continue to demonstrate technical competency to maintain recognition. If monitoring of a 3P510k Review Organization reveals nonconformity with section 523, a threat to the public health, or a failure to act in a manner that is consistent with the purposes of section 523 of the FD&C Act, FDA may take steps to suspend or withdraw recognition of the 3P510k Review Organization, after providing notice and an opportunity for an informal hearing. See section 523(b)(2)(B) of the FD&C Act.

⁹⁶ See section 523(b)(2)(D)(i) of the FD&C Act.

X. Leveraging the International Medical Device Regulators Forum's (IMDRF's) documents

In February 2011, the IMDRF was convened to discuss future directions in medical device regulatory harmonization. The IMDRF is a voluntary group of medical device regulators from around the world, including representatives from the FDA, who collaborate to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices. The purpose of the IMDRF is to accelerate international medical device regulatory convergence.

The IMDRF Medical Device Single Audit Program (MDSAP) and Good Regulatory Review Practices (GRRP) working groups developed documents that provide the fundamental building blocks of a 3P510k program by providing criteria for reviewer competence, training, and conduct, and, for organizations, the recognition and monitoring of entities that perform regulatory audits and other related functions. Details are outlined in a collection of documents finalized from 2013 through 2019 and available on the IMDRF website.⁹⁷

There are many shared elements in FDA's statutory and regulatory criteria for 3P510k Review Organizations and IMDRF MDSAP WG/N3 FINAL: 2016 (Edition 2): "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition"⁹⁸ and IMDRF IMDRF GRRP WG/N40 FINAL:2017: "Competence, Training, and Conduct Requirements for Regulatory Reviewers."⁹⁹ These two documents focus on requirements of an auditing organization and of individuals performing regulatory reviews and other related functions under the respective medical device legislation, regulations, and procedures required in its regulatory jurisdiction.

Due to these similarities, FDA believes that potential 3P510k Review Organizations in compliance with the GRRP and MDSAP documents, as appropriate, are likely to be in compliance with most FDA 3P510k Review Organization requirements and meet FDA's recommendations outlined in this guidance document. Such organizations do not necessarily need to generate new documentation for FDA, but rather can leverage existing documents in their applications to FDA and for ongoing recordkeeping.

⁹⁷ As of the publication of this guidance document, the IMDRF has published eight documents related to MDSAP and three documents related to GRRP. All the IMDRF documents are available on the IMDRF website at:<http://imdrf.org/documents/documents.asp>. This guidance references IMDRF GRRP WG N40 Final:2017, "Competence, Training, and Conduct Requirements for Regulatory Reviewers", and IMDRF MDSAP WG N3 Final:2016, "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition."

⁹⁸ IMDRF MDSAP Working Group N3 Final: 2016 (Edition 2): "Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition", previously cited, can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160324-requirements-auditing-orar.pdf>.

⁹⁹ IMDRF/GRRP WG/N40 FINAL:2017: "Competence, Training, and Conduct Requirements for Regulatory Reviewers", previously cited, can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf>.

XI. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to be 24 hours to submit requests for accreditation, 24 hours to submit requests for reaccreditation, 40 hours to submit 510(k) reviews by 3P510k Review Organizations to FDA, and 15 minutes to submit complaints to FDA. In addition, the time required to complete this information collection with respect to recordkeeping is estimated to be 10 hours for maintaining records of 510(k) reviews and 1 hour for maintenance of Records regarding qualifications to receive FDA recognition as a 3PRO, and 2 hours for maintenance of a recordkeeping system regarding complaints.

Send comments regarding this burden estimate or suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0375.