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Classification of Posterior Cervical Screw Systems: Small Entity Compliance Guide

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact Regulations, Policy, and Guidance Staff by email at RPG@fda.hhs.gov.

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

Preface

Public Comment

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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

On April 1, 2019, FDA published a final rule in the **Federal Register** entitled "Classification of Posterior Cervical Screw Systems" (84 FR 12088). This final rule created the classification regulation 21 CFR 888.3075 for posterior cervical screw systems and established special controls. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28) to assist small entities to comply with the requirements established in 21 CFR 888.3075.

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

Prior to the classification, FDA regulated posterior cervical screw systems as unclassified preamendments devices requiring premarket notification (510(k)).

On April 9, 2009, FDA published an order under sections 515(i) and 519 of the FD&C Act (515(i) order) for the submission of safety and effectiveness information on pedicle screw spinal systems with certain indications for use (74 FR 16214). In response to that order, FDA received a request from the Orthopedic Surgical Manufacturers Association (OSMA) to

classify posterior cervical screw systems into class II (special controls). Because this request was considered to be outside the scope of the 515(i) order related to pedicle screw spinal systems, FDA requested that OSMA submit a separate petition for classification of posterior cervical screw systems. OSMA submitted the requested petition on November 22, 2011, under Docket No. FDA-2011-P-0851. FDA convened an advisory committee meeting of the Orthopaedic and Rehabilitation Devices Panel (the Panel) regarding the classification of this device type on September 21, 2012. At that meeting, the Panel recommended that posterior cervical screw systems be classified as class II with special controls. On April 1, 2019, FDA published a final rule to classify posterior cervical screw systems into class II (special controls) (84 FR 12088).[1]

III. Classification of Posterior Cervical Screw Systems

A. Classification Regulation

The classification regulation for posterior cervical screw systems is 21 CFR 888.3075.[2] The regulation classifies posterior cervical screw systems (product code NKG) into class II (special controls).

B. Identification of Posterior Cervical Screw Systems

Paragraph (a) of §888.3075 identifies posterior cervical screw systems.

C. Posterior Cervical Screw Systems Class and Special Controls

Paragraph (b) of §888.3075 establishes the class and special controls for posterior cervical screw systems.

While posterior cervical screw systems[3] must comply with the special controls,[4] it is not expected that manufacturers of devices already on the market as of May 1, 2019, would need to submit new 510(k)s, 510(k) amendments, or add-to-files to demonstrate conformance with the special controls.[5]

D. Posterior Cervical Screw System Classification Regulation Effective Date

The classification rule became effective May 1, 2019.

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[1] Available at https://www.regulations.gov/document?D=FDA-2015-N-3785-0009.
[2] https://gov.ecfr.io/cgi-bin/retrieveECFR?gp=1&SID=068f27da33775aedfe34920c57076d02&ty=HTML&h=L&mc=true&r=SECTION&n=se21.8.888_13075
[3] As identified in 21 CFR 888.3075(a)
[4] Section 513(a)(1)(B) of the FD&C Act, 21 U.S.C. 360c(a)(1)(B)
[5] 84 FR 12088 at 12090, April 1, 2019

E. Viewing the Posterior Cervical Screw System Classification Regulation

The United States government provides an electronic version of the Code of Federal Regulations (eCFR). The posterior cervical screw system regulation can be found in the eCFR.[6] The title number is 21. The section heading is 888.3075.

[6] https://gov.ecfr.io/cgi-bin/ECFR?SID=faf9398779e536bc9e7700b3cbc2ed79&mc=true&page=simple