

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 888****[Docket No. FDA-2024-N-3994]****Medical Devices; Orthopedic Devices; Classification of the Intervertebral Body Graft Containment Device****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the intervertebral body graft containment device into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the intervertebral body graft containment device's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective September 3, 2024. The classification was applicable on September 18, 2020.

FOR FURTHER INFORMATION CONTACT: Aakash Jain, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4566, Silver Spring, MD 20993-0002, 240-402-7531, Aakash.Jain@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Upon request, FDA has classified the intervertebral body graft containment device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments

devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the 510(k) process, when necessary, to market their device.

II. De Novo Classification

On February 19, 2020, FDA received Spineology, Inc.'s request for De Novo classification of the Spineology Interbody Fusion System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on September 18, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 888.3085.¹ We have named the generic type of device intervertebral body graft containment device, and it is identified as a non-rigid, implanted spinal device that is designed to contain bone graft within its internal cavity. The device is inserted into the intervertebral body space of the spine and is intended as an adjunct to intervertebral body fusion.

FDA has identified the following risks to health associated specifically with

¹ FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to

indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—INTERVERTEBRAL BODY GRAFT CONTAINMENT DEVICE RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Adverse tissue reaction	Design characteristics, Biocompatibility evaluation, Sterilization/reprocessing validation, and Labeling.
Infection	Sterilization/reprocessing validation and Labeling.
Loosening/migration due to device failure or failure at the bone-implant interface	Design characteristics, Clinical performance testing, Non-clinical performance testing, Biocompatibility evaluation, and Labeling.
Tissue injury	Labeling.
Pseudarthrosis due to device failure or failure at the bone-implant interface	Clinical performance testing, Non-clinical performance testing, Biocompatibility evaluation, and Labeling.
Adverse clinical sequelae	Clinical performance testing and Labeling.
Use error/Improper device use	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control

number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 888.3085 to read as follows:

§ 888.3085 Intervertebral body graft containment device.

(a) *Identification.* An intervertebral body graft containment device is a non-rigid, implanted spinal device that is designed to contain bone graft within its internal cavity. The device is inserted into the intervertebral body space of the spine and is intended as an adjunct to intervertebral body fusion.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must include an assessment of any adverse events observed during clinical use, as well as intervertebral body fusion, and compare this to a clinically acceptable fusion rate.

(2) Non-clinical performance testing must demonstrate the mechanical function and durability of the implant, as well as the ability of the device to be inserted, deployed, and filled with bone graft consistently.

(3) Device must be demonstrated to be biocompatible.

(4) Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components, and device-specific instruments.

(5) Design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.

(6) Labeling must bear all information required for the safe and effective use of the device, specifically including the following:

(i) A clear description of the technological features of the device including identification of device materials, compatible components in the fusion construct, and the principles of device operation;

(ii) Intended use and indications for use, including levels of fixation;

(iii) Identification of magnetic resonance (MR) compatibility status;

(iv) Cleaning and sterilization instructions for devices and instruments that are provided nonsterile to the end user; and

(v) Detailed instructions of each surgical step, including device removal.

Dated: August 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2024–N–3946]

Medical Devices; Physical Medicine Devices; Classification of the External Compression Device for Internal Jugular Vein Compression

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the external compression device for internal jugular vein compression into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the external compression device for internal jugular vein compression's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective September 3, 2024. The classification was applicable on February 26, 2021.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the external compression device for internal jugular vein compression as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is

automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo

classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 19, 2020, FDA received Q30 Sports Science's request for De Novo classification of the Q-Collar. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 26, 2021, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 890.3050.¹ We have named the generic type of device external compression device for internal jugular vein compression, and it is identified as a non-invasive device that is intended to increase intracranial blood volume to reduce the occurrence of specific changes in the brain following head

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