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 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in the guidance document ''Medical Device Accessories—Describing Accessories and Classification Pathways'' have been approved under OMB control number 0910–0823; the collections of information in part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 regarding quality system regulation have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; and the collections of information in 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, 360*l,* 371.

■ 2. Add § 888.4520 to subpart E to read as follows:

§ 888.4520 Orthopedic manual surgical instrumentation for use with non-fusion spinous process spacer devices.

(a) *Identification.* Orthopedic manual surgical instrumentation for use with non-fusion spinous process spacer devices are non-powered hand-held devices designed specifically for use with non-fusion spinous process spacer devices and interface with the associated implant for the purpose of inserting, positioning, or removing the implant. This type of device includes instruments specific to the geometry of the implant.

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

(1) Technical specifications regarding geometry of the instruments must be specified and validated to demonstrate that the instruments can safely position, place, or remove the implant.

(2) The patient contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate that reprocessing of reusable devices that are provided non-sterile, or sterilization of devices provided sterile, is validated.

(4) Labeling must include:

(i) Identification of implant(s) and instruments which have been validated for use together; and

(ii) Validated methods and instructions for reprocessing any reusable parts.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16040 Filed 8–20–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2025–N–2520]

Medical Devices; Orthopedic Devices; Classification of Orthopedic Manual Surgical Instrumentation for Use With Total Disc Replacement Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying orthopedic manual surgical instrumentation for use with total disc replacement devices 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 classification of orthopedic manual surgical instrumentation for use with total disc replacement devices. We are taking this action because we have determined that classifying the device into class II 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, in part by reducing regulatory burdens.

DATES: This order is effective August 21, 2025. The classification was applicable on June 24, 2020.

FOR FURTHER INFORMATION CONTACT: Michael Molyneaux-Francis, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4508, Silver Spring, MD 20993–0002, 240–402–5178, *Michael.Molyneaux-francis@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified orthopedic manual surgical instrumentation for use with total disc replacement devices as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness for its intended use. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into the appropriate device class based on risk and the regulatory controls sufficient to provide reasonable assurance of safety and effectiveness.

FDA may classify a device through an accessory classification request under section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(6)), established by section 707 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52). The provision allows manufacturers or importers to request classification of an accessory distinct from another device upon written request. The classification is based on the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request appropriate classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days announcing the classification.

Alternatively, under section 513(f)(6)(C) of the FD&C Act, a person

filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days announcing the classification.

II. Accessory Classification

On March 31, 2020, FDA received Spinal Kinetics LLC's request for accessory classification of M6–C Artificial Cervical Disc Instrumentation. 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 section 513(a)(1)(B) of the FD&C Act). 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 June 24, 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 888.4515.[1] We have named the generic type of device ''orthopedic manual surgical instrumentation for use with total disc replacement devices,'' and they are identified as non-powered hand-held devices designed specifically for use with a total disc replacement device and interface with the associated implant for the purpose of insertion, removal, placement, or repositioning, or to cut, rasp, or create a defect specific to the features of the associated implant. This type of device includes instruments specific to the geometry of the implant.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—ORTHOPEDIC MANUAL SURGICAL INSTRUMENTATION FOR USE WITH TOTAL DISC REPLACEMENT DEVICES RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Infection	Reprocessing validation, Sterilization validation, and Labeling.
Implant damage or malpositioning	Validation of technical specifications, and 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 final order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act (21 U.S.C. 360(k)).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. At a future date, we may publish a separate notice in the **Federal Register** announcing our intent to exempt this device.

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 the guidance document ''Medical Device Accessories–Describing Accessories and Classification Pathways'' have been approved under OMB control number 0910–0823; the collections of information in part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 regarding quality system regulation have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; and the collections of information in part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 888

Medical devices.

[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.

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 § 888.4515 to subpart E to read as follows:

§ 888.4515 Orthopedic manual surgical instrumentation for use with total disc replacement devices.

(a) *Identification.* Orthopedic manual surgical instrumentation for use with total disc replacement devices are non-powered hand-held devices designed specifically for use with a total disc replacement device and interface with the associated implant for the purpose of insertion, removal, placement, or repositioning, or to cut, rasp, or create a defect specific to the features of the associated implant. This type of device includes instruments specific to the geometry of the implant.

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

(1) Technical specifications regarding geometry of the instruments must be specified and validated to demonstrate that the instruments can safely position, place, or remove the implant.

(2) The patient contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate that reprocessing of reusable devices that are provided non-sterile, or sterilization of devices provided sterile, is validated.

(4) Labeling must include:

(i) Identification of implant(s) and instruments which have been validated for use together; and

(ii) Validated methods and instructions for reprocessing any reusable parts.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16039 Filed 8–20–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA–2025–N–2369]

Medical Devices; Radiology Devices; Classification of the Liver Iron Concentration Imaging Companion Diagnostic for Deferasirox

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the liver iron concentration imaging companion diagnostic for deferasirox 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 classification of the liver iron concentration imaging companion diagnostic for deferasirox. We are taking this action because we have determined that classifying the device into class II 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, in part by reducing regulatory burdens.

DATES: This order is effective August 21, 2025. The classification was applicable on January 23, 2013.

FOR FURTHER INFORMATION CONTACT: Daniel Krainak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3674, Silver Spring, MD 20993–0002, 301–796–0478, *Daniel.Krainak@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the liver iron concentration imaging companion diagnostic for deferasirox as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

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 (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 (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