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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2022–N–0114]

Medical Devices; Orthopedic Devices; Classification of the Screw Sleeve Bone Fixation 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 screw sleeve bone fixation 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 screw sleeve bone fixation 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 March 1, 2022. The classification was applicable on May 1, 2020.

FOR FURTHER INFORMATION CONTACT: Jesse Muir, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4508, Silver Spring, MD 20993–0002, 240–402–6679, *Jesse.Muir@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the screw sleeve bone fixation device 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, 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 (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 (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. 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 less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On December 13, 2018, FDA received Woven Orthopedic Technologies, LLC's request for De Novo classification of the OGmend® Implant 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 May 1, 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 888.3043.[1] We have named the generic type of device ''screw sleeve bone fixation device,'' and it is intended to be implanted in conjunction with a non-resorbable, metallic bone screw where the screw has lost purchase due to loosening, backout, or breakage. The device fits between the screw threads and surrounding bone and provides increased surface area to create an

[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.

interference fit to restore stability of the implant construct.

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—SCREW SLEEVE BONE FIXATION DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Loss of function/mechanical integrity resulting from: ▪ Device malposition. ▪ Device breakage. ▪ Damage to screw during insertion. ▪ Deterioration due to aging. ▪ Insufficient restoration of screw fixation.	In vivo performance testing; Non-clinical performance testing; Shelf life testing; and Labeling.
Revision	In vivo performance testing; Non-clinical performance testing; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation; In vivo performance testing; Non-clinical performance testing; and Labeling.
Infection	Sterilization validation; and Shelf life testing.
Febrile response due to endotoxins	Pyrogenicity testing.

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. We encourage sponsors to consult with us if they wish to use a non-animal testing method that they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method. 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 21 CFR 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 § 888.3043 to subpart D to read as follows:

§ 888.3043 Screw sleeve bone fixation device.

(a) *Identification.* A screw sleeve bone fixation device is intended to be implanted in conjunction with a non-resorbable, metallic bone screw where the screw has lost purchase due to loosening, backout, or breakage. The device fits between the screw threads and surrounding bone and provides increased surface area to create an interference fit to restore stability of the implant construct.

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

(1) In vivo performance testing under anticipated conditions of use must demonstrate:

(i) The device provides sufficient stability to allow for fracture healing; and

(ii) A lack of adverse biologic response to the implant through histopathological and histomorphometric assessment.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must:

(i) Assess the stability of the device in a rescue screw scenario;

(ii) Demonstrate that the device can be inserted and removed without damage to the implant or associated hardware;

(iii) Demonstrate the device can withstand dynamic loading without device failure; and

(iv) Characterize wear particle generation.

(3) The device must be demonstrated to be biocompatible.

(4) The device must be demonstrated to be non-pyrogenic.

(5) Performance data must demonstrate the sterility of the device.

(6) Performance data must support the labeled shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the established shelf life.

(7) Labeling must include:

(i) A detailed summary of the device technical parameters;

(ii) Information describing all materials of the device;

(iii) Instructions for use, including device removal; and

(iv) A shelf life.

Dated: February 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04154 Filed 2–28–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA–2019–N–3065]

RIN 0910–AI39

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Delayed Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: As required by an order issued by the U.S. District Court for the Eastern District of Texas, this action delays the effective date of the final rule (''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements''), which published on March 18, 2020. The new effective date is April 9, 2023.

DATES: The effective date of the rule amending 21 CFR part 1141 published at 85 FR 15638, March 18, 2020, and delayed at 85 FR 32293, May 29, 2020; 86 FR 3793, January 15, 2021; 86 FR 36509, July 12, 2021; 86 FR 50855, September 13, 2021; and 86 FR 70052, December 9, 2021, is further delayed until April 9, 2023.

FOR FURTHER INFORMATION CONTACT: Courtney Smith, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1371, email: *CTPRegulations@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 18, 2020, the Food and Drug Administration (FDA or Agency) issued a final rule establishing new cigarette health warnings for cigarette packages and advertisements. The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act of 1965 (Pub. L. 89–92) to require each cigarette package and advertisement to bear one of the new required warnings. The final rule specifies the 11 new textual warning label statements and accompanying color graphics. Pursuant to section 201(b) of the Tobacco Control Act, the rule was published with an effective date of June 18, 2021, 15 months after the date of publication of the final rule.

On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.[1] On May 8, 2020, the court granted a joint motion to govern proceedings in that case and postpone the effective date of the final rule by 120 days.[2] On December 2, 2020, the court granted a new motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.[3] On March 2, 2021, the court granted another motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.[4] On May 21, 2021, the court granted another motion by the plaintiffs to postpone the effective date of the final rule by an additional 90 days.[5] On August 18, 2021, the court issued an order to postpone the effective date of the final rule by an additional 90 days.[6] On November 12, 2021, the court issued another order to postpone the effective date of the final rule by an additional 90 days.[7] On February 10, 2022, the court issued another order to postpone the effective date of the final rule by an additional 90 days.[8] The court ordered that the new effective date of the final rule is April 9, 2023. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date.

To the extent that 5 U.S.C. 553 applies to this action, the Agency's implementation of this action without opportunity for public comment, effective immediately upon publication in the **Federal Register**, is based on the good cause exception in 5 U.S.C. 553(b)(B). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The 90-day postponement of the effective date, until April 9, 2023, is required by court order in accordance with the court's authority to postpone a rule's effective date pending judicial review (5 U.S.C. 705). Seeking prior public comment on this postponement would have been impracticable, as well as contrary to the public interest in the orderly issuance and implementation of regulations.

Dated: February 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04181 Filed 2–28–22; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[TD 9962]

RIN 1545–BQ06

User Fees Relating to the Enrolled Agent Special Enrollment Examination and the Enrolled Retirement Plan Agent Special Enrollment Examination

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: These final regulations amend existing regulations relating to the user fees for the special enrollment examinations for enrolled agents and enrolled retirement plan agents. The final regulations increase the amount of the user fee for each part of the special enrollment examination for enrolled agents (EA SEE). The final regulations also remove the user fee for the special enrollment examination for enrolled retirement plan agents (ERPA SEE) because the IRS no longer offers the ERPA SEE or new enrollment as an enrolled retirement plan agent. The final regulations affect individuals taking the EA SEE. The Independent Offices Appropriation Act of 1952 authorizes charging user fees.

DATES: *Effective date:* These regulations are effective March 31, 2022.

Applicability date: For the date of applicability, see § 300.4(d).

[1] *R.J. Reynolds Tobacco Co. et al.* v. *United States Food and Drug Administration et al.,* No. 6:20–cv–00176 (E.D. Tex. filed April 3, 2020).

[2] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

[3] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. December 2, 2020) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 80.

[4] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. March 2, 2021) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 89.

[5] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. May 21, 2021) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 91.

[6] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. August 18, 2021) (order postponing effective date), Doc. No. 92.

[7] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. November 12, 2021) (order postponing effective date), Doc. No. 93.

[8] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. February 10, 2022) (order postponing effective date), Doc. No. 94.