DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2021–N–0309]

Effective Date of Requirement for Premarket Approval Applications for Spinal Spheres for Use in Intervertebral Fusion Procedures

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed amendment; proposed order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to require the filing of a premarket approval application (PMA) for spinal spheres for use in intervertebral fusion procedures, which is an unclassified, preamendments device. FDA is summarizing its proposed findings regarding the degree or risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the PMA requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the benefits to the public from the use of the device.

DATES: Submit either electronic or written comments on the proposed order by March 15, 2022. FDA intends that, if a final order based on this proposed order is issued, anyone who wishes to market spinal spheres for use in intervertebral fusion procedures will need to submit a PMA prior to the last day of the 30th calendar month beginning after the month in which the classification of the device in class III became effective. See section III for the effective date of any final order that may publish based on this proposed order. See section VI of this document for more information about submitting a PMA.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 15, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 15, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions.'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0309 for ''Effective Date of Requirement for Premarket Approval Applications for Spinal Spheres for Use in Intervertebral Fusion Procedures.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Constance Soves, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1656, Silver Spring, MD 20993–0002, 301–796–6951, *Constance.Soves@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The FD&C Act, as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d)(1) of the FD&C Act, devices that were in commercial distribution before the enactment on May 28, 1976 of the 1976 amendments

(Medical Device Amendments of 1976, Pub. L. 94–295), (generally referred to as ''preamendments devices''), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

A person may market a preamendments device that has been classified into class III through premarket notification procedures, without submission of a PMA until FDA issues an administrative order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 515(f) of the FD&C Act provides an alternative pathway for meeting the premarket approval requirement. Under section 515(f), manufacturers may meet the premarket approval requirement, if they file a notice of completion of a product development protocol (PDP) approved under section 515(f)(4) of the FD&C Act and FDA declares the PDP completed under section 515(f)(6)(B) of the FD&C Act. Accordingly, the manufacturer of a preamendments class III device may comply with a call for PMAs by filing a PMA or a notice of completion of a PDP. In practice, however, the option of filing a notice of completion of a PDP has rarely been used. For simplicity, although the PDP option remains available to manufacturers in response to a final order under section 515(b) of the FD&C Act, this document will refer only to the requirement for filing and obtaining approval of a PMA.

Section 515(b)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order requiring premarket approval for a preamendments class III device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments from all affected stakeholders, including patients, payors, and providers.

Section 515(b)(2) of the FD&C Act provides that a proposed order to require premarket approval shall contain: (1) The proposed order; (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed order and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed order,[1] consideration of any comments received, and a meeting of a device classification panel described in section 513(b) of the FD&C Act, issue a final order to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the FD&C Act, unless the reason for termination is that the device is a banned device under section 516 of the FD&C Act (21 U.S.C. 360f).

A preamendments class III device may be commercially distributed without a PMA until 90 days after FDA issues a final order requiring premarket approval for the device, or 30 months after the classification of the device in class III under section 513 of the FD&C Act becomes effective, whichever is later (section 501(f)(2)(B) of the FD&C Act (21 U.S.C. 351(f)(2)(B)). Elsewhere in this issue of the **Federal Register**, FDA is proposing to classify spinal spheres for use in intervertebral fusion procedures (spinal spheres) to class III. Therefore, if the proposed classification regulation and the order to require PMAs are finalized at the same time, a PMA for spinal spheres for use in intervertebral fusion procedures must be filed within the 30-month period because that will be the later of the two time periods. If a PMA is not timely filed for such devices, then the device would be deemed adulterated under section 501(f) of the FD&C Act.

Also, a preamendments device subject to the order process under section 515(b) of the FD&C Act is not required to have an approved investigational device exemption (IDE) (see part 812 (21 CFR part 812)) contemporaneous with its interstate distribution until the date identified by FDA in the final order requiring the filing of a PMA for the device. At that time, an IDE is required only if a PMA has not been filed. If the manufacturer, importer, or other sponsor of the device submits an IDE application and FDA approves it, the device may be distributed for investigational use. If a PMA is not filed by the later of the two dates, and the device is not distributed for investigational use under an IDE, the device is deemed adulterated within the meaning of section 501(f)(1)(A) of the FD&C Act and subject to enforcement action.

[1] In December 2019, FDA began adding the term ''Proposed amendment'' to the ''ACTION'' caption for these documents to indicate that they ''propose to amend'' the Code of Federal Regulations. This editorial change was made in accordance with the Office of the Federal Register's 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.

II. Regulatory History of the Devices

After the enactment of the Medical Device Amendments of 1976, FDA undertook an effort to identify and classify all preamendments devices, in accordance with section 513(d) of the FD&C Act. FDA issued a proposed rule for classification of 77 generic types of orthopedic devices in the **Federal Register** of September 4, 1987 (52 FR 33686). However, spinal spheres for use in intervertebral fusion procedures were not identified in this effort. Subsequently and consistent with the FD&C Act, FDA held a panel meeting on December 12, 2013, regarding the classification of spinal sphere devices for use in intervertebral fusion procedures (Ref. 1). Spinal sphere devices, intended for use in fusion procedures, are no longer used due to the widespread adoption of intervertebral body fusion devices (''interbody cages''). Unlike spinal sphere devices, interbody cages generally possess different features to engage with vertebral endplates, allowing them to resist migration and subsidence, and features that allow for the packing of graft material, facilitating bone growth into and through the device.

Elsewhere in this issue of the **Federal Register**, FDA is proposing to classify unclassified, preamendment spinal spheres for use in intervertebral fusion procedures into class III. A PMA, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device. The proposed rule would also establish the identification, classification, and regulatory controls for spinal spheres.

Spinal spheres for use in intervertebral fusion procedures are unclassified preamendments devices. These devices have been subject to premarket review through a 510(k) submission and have been cleared for marketing if FDA considers the device to be substantially equivalent to a legally marketed predicate in accordance with section 513(i) of the FD&C Act. To date, FDA has cleared six spinal sphere devices from four manufacturers.

On December 12, 2013, FDA convened the Orthopaedic and Rehabilitation Devices Panel (the Panel) to secure recommendations regarding the appropriate classification, regulatory controls, as well as risks to health and benefits of spinal spheres (Ref. 1). At the meeting, FDA requested that the Panel consider whether this device type fits the statutory definition for a class III device. The Panel considered the information provided by FDA about spinal spheres, including results and analysis from a literature search and search of known adverse events (Ref. 1).

The Panel unanimously recommended that spinal spheres be classified into class III, subject to PMA. The Panel believed that classification in class III is appropriate given that there was a lack of available evidence to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness for use in intervertebral body fusion procedures. Furthermore, the Panel unanimously agreed that spinal spheres for use in fusion procedures present an unreasonable risk of illness or injury to the patients. In addition to the risks to health identified by FDA that include removal/revision, pain, and neurologic impairment, the Panel recommended incorporating all known risks generally associated with spinal interbody fusion procedures (see Ref. 1, Panel transcript at page 58).

In summary, the Panel unanimously determined that given the lack of available evidence and unreasonable risk profile of spinal spheres devices for use in fusion procedures, these devices should be classified as class III devices, which would, after publication of a final order calling for PMAs, require submission of a PMA application and approval to market the device. FDA agrees with the Panel's recommendation that there was a lack of available evidence to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, and that the device presents a potential unreasonable risk of illness or injury. FDA further agrees with the Panel's recommendation that spinal sphere devices for use in fusion procedures be classified into class III subject to PMA.

III. Dates New Requirements Apply

If FDA finalizes the proposed classification of spinal spheres, these devices will be classified into class III. In accordance with sections 501(f)(2)(B) and 515(b) of the FD&C Act, FDA is proposing to require that a PMA be filed with the Agency for spinal sphere devices by the last day of the 30th calendar month beginning after the month in which the classification of the device in class III became effective. An applicant whose product was legally in commercial distribution before May 28, 1976, or whose product has been found to be substantially equivalent to such a product, will be permitted to continue marketing such class III product during FDA's review of the PMA, provided that a PMA is timely filed. FDA intends to review any PMA for the device within 180 days. FDA cautions that under section 515(d)(1)(B)(i) of the FD&C Act, the Agency may not enter into an agreement to extend the review period for a PMA beyond 180 days, unless the Agency finds that ''. . . the continued availability of the device is necessary for the public health.''

If a PMA for a class III device is not filed with FDA within 30 months after the classification of the device into class III, commercial distribution of the device must cease. The device may be distributed for investigational use, only if the requirements of the IDE regulations in part 812 are met. The requirements for investigational use of significant risk devices include submitting an IDE application to FDA for review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued under 21 CFR 812.30. FDA, therefore, recommends that IDE applications be submitted to FDA at least 30 days before the date a PMA is required to be filed to avoid interrupting investigations.

IV. Device Subject to This Proposal

A spinal sphere is a prescription device that is an implanted, solid, spherical device manufactured from metallic (*e.g.,* cobalt-chromium-molybdenum (CoCrMo)) or polymeric (*e.g.,* polyetheretherketone (PEEK)) materials. They are intended to be inserted into the intervertebral disc space of the lumbar spine following a discectomy in order to maintain disc space height and provide postoperative stabilization to the affected spinal segment during fusion procedures. The device is to be used with bone graft material. FDA currently regulates these unclassified devices as devices requiring a 510(k) submission under product code NVR.

Elsewhere in this issue of the **Federal Register**, FDA is proposing to classify spinal spheres in class III and identifies these devices as follows: A spinal sphere device is an implanted, solid, spherical, prescription device manufactured from metallic or polymeric materials. The device is inserted into the intervertebral body space of the lumbar spine to provide stabilization and to help promote intervertebral body fusion. The device is to be used with bone graft material.

In accordance with section 515(b)(2)(D) of the FD&C Act, interested persons are being offered the opportunity to comment or request a change on the Agency's proposed classification of spinal spheres based on new information published elsewhere in this **Federal Register**.

V. Proposed Findings With Respect to Risks and Benefits for Spinal Spheres for Use in Intervertebral Fusion Procedures

As required by section 515(b) of the FD&C Act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA and (2) the benefits to the public from the use of the devices. These findings are based on the reports and recommendations of the Orthopaedic and Rehabilitation Devices Panel meeting on December 12, 2013 (Ref. 1), and any additional information that FDA has obtained. Additional information regarding the risks can be found below, as well as in the proposed rule published elsewhere in this issue of the **Federal Register**, proposing to classify these devices into class III.

Based on this information, FDA has identified and proposes the following risks to health for spinal spheres:

Reoperation: The need for reoperation could result from a failed spinal sphere device or component of the device, from nerve root decompression or adjacent level disease, or from reasons related to any surgery, *e.g.,* infection or bleeding.

Pain and loss of function: Some device-related complications that may cause pain and loss of function include device fracture, deformation, loosening, or extrusion. The wear of materials, which may cause osteolysis (dissolution of bone), and component disassembly, fracture, or failure may also result in pain and loss of function.

Infection: Infection of the soft tissue, bony tissue, and the disc space may arise due to implantation of a spinal sphere device. Material composition or impurities, wear debris, operative time, and operative environment may compromise the vascular supply to the area or affect the immune system, which could increase the risk of infection. Improper sterilization or packaging may also increase the risk of infection.

Adverse tissue reaction: The implantation of the spinal sphere device will elicit a mild inflammatory reaction typical of a normal foreign body

response. Incompatible materials or impurities in the materials and wear debris may increase the severity of a local tissue reaction or cause a systemic tissue reaction. If the materials used in the manufacture of the spinal sphere device are not biocompatible, the patient could have an adverse tissue reaction.

Soft tissue injury: Soft tissue injury could include injury to major blood vessels, viscera, nerve roots, spinal cord, and cauda equina.

Vertebral endplate injury: Surgically inserting a device with a different geometry and modulus of elasticity than bone may lead to vertebral fracture, sinking of the device into the vertebral endplate (subsidence), collapse of the local blood supply, and collapse of the vertebral end plate.

Pseudarthrosis: Pseudarthrosis (*i.e.,* non-union) signifies failure of the bony fusion mass and results in persistent instability.

Implant migration and/or instability: The spinal sphere device may not adequately stabilize the disc space and may migrate out of its intended placement as it is a spherical implant inserted between the parallel vertebral endplates. This may lead to subsequent adverse clinical sequelae, such as pain or loss of function or pseudarthrosis.

Implant breakage during insertion: The device may fracture during implantation, which could result in a mechanical or functional failure. This may lead to subsequent adverse clinical sequelae, such as neurologic, vascular, or osseous injury.

A. Summary of Data

FDA conducted queries of the Manufacturer and User Facility Device Experience (MAUDE) database to identify adverse events related to use of spinal spheres. The queries resulted in the identification of 21 unique Medical Device Reports (MDRs) on spinal sphere devices at the time of the Panel meeting. Of these 21 MDRS, 18 were reported as injuries and 3 as malfunctions. Three additional MDRs have been reported under this product code since the previous review of the MAUDE database prior to the Panel meeting. One report reflects use of a spinal sphere device without fusion that was also reported in the literature as discussed below. One report was regarding devices that were not spinal spheres, and the remaining report was unclear on the device that caused the event.

Additionally, FDA conducted a comprehensive literature review to identify and gather relevant published information regarding the safety and effectiveness of spinal sphere devices for use in fusion procedures. However, no references specifically describing spinal sphere devices for use in fusion procedures were identified. A contemporary search using the same parameters yielded a similar result. Of note, one article, a case study of a patient implanted with a spinal sphere, reflected one of the MDRs reported above; however, this patient did not undergo spinal fusion in conjunction with implantation of the device (Ref. 2). Consequently, FDA concludes there is inadequate information characterizing the safety and effectiveness of spinal sphere devices when used for fusion procedures. The 510(k) clearances of these devices were based solely on nonclinical information and determinations of substantial equivalence to the preamendments device in accordance with section 513(i) of the FD&C Act, which, in light of the available information regarding the risks with no information supporting the benefit of these devices, is inadequate to support a reasonable assurance of safety and effectiveness for these devices.

Subsequently, on December 12, 2013, FDA convened the Orthopaedic and Rehabilitation Panel described in section I (Ref. 1). The Panel unanimously concluded that there was a lack of available evidence to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness for spinal sphere devices for use in fusion procedures. Furthermore, the Panel unanimously agreed that because spinal sphere devices for use in fusion procedures present an unreasonable risk of illness or injury to the patient given the lack of probable benefit, spinal spheres should be classified into class III.

B. Benefits of the Device

The purported benefit of use of spinal spheres for use in intervertebral fusion procedures is to provide stabilization of a spinal segment, as an adjunct to fusion; however, FDA is not aware of evidence supporting the stated benefit of spinal spheres for use in fusion procedures. FDA is proposing a PMA be filed to require that manufacturers demonstrate that a reasonable assurance of safety and effectiveness exists for spinal spheres.

C. Risks to Health

The Panel unanimously determined that there was a lack of available evidence to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, and that the device presents a potential unreasonable risk of illness or injury. The unreasonable risk profile of spinal spheres devices for use in fusion procedures includes reoperation, pain and loss of function, infection, adverse tissue reaction, soft tissue injury, vertebral endplate injury, pseudarthrosis, implant migration and/or instability, and implant breakage during insertion. FDA agrees with the Panel's recommendation that insufficient information exists FDA further agrees with the Panel's recommendation that spinal sphere devices for use in fusion procedures be classified into class III subject to PMA.

VI. PMA Requirements

A PMA for spinal sphere devices for use in fusion procedures must include the information required by section 515(c)(1) of the FD&C Act. Such a PMA should also include a detailed discussion of the risks identified in section V, as well as a discussion of the effectiveness of the product for which premarket approval is sought. In addition, a PMA must include all data and information on the following: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA must include valid scientific evidence to demonstrate reasonable assurance of the safety and effectiveness of the spinal sphere for its intended use (see § 860.7(c)(2) (21 CFR 860.7(c)(2))). FDA defines valid scientific evidence in § 860.7(c)(2).

To present reasonable assurance of safety and effectiveness of spinal sphere devices, FDA tentatively concludes that manufacturers should submit performance testing, including clinical trials of their product, in order to support PMA approval. Existing published clinical literature relevant to the product may also be leveraged as part of the PMA submission. In addition, FDA strongly encourages manufacturers to meet with the Agency early through the Q-Submission Program for any assistance in preparation of their PMA.

VII. Analysis of Environmental Impact

We have 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.

VIII. Paperwork Reduction Act of 1995

While this proposed order contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by the OMB under the PRA. The collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; and the collections of information in part 812 have been approved under OMB control number 0910–0078.

IX. Proposed Effective Date

FDA is proposing that any final order based on this proposal become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final order.

X. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA or notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(D) of the FD&C Act to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to the classification. A request for a change in the classification of spinal spheres for use in intervertebral fusion procedures should be provided in response to the proposed rule issued elsewhere in this issue of the **Federal Register** and contain the information required by 21 CFR 860.123, including new information relevant to the classification of the device.

XI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. *Orthopaedic and Rehabilitation Devices Panel—Classification of Spinal Sphere Devices Meeting, December 12, 2013, available at *https://wayback.archive-it.org/7993/20170114044038/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM378083.pdf.*

2. Lindley, E.M., B. Levy, E.L. Burger, et al., ''Failure of the Fernstrom Ball in Contemporary Spine Surgery: A Case of History Repeating Itself.'' *Current Orthopaedic Practice,* 25(1): 87–91, 2014.

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, we propose that 21 CFR part 888 be 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. In § 888.3085, add paragraph (c) to read as follows:

§ 888.3085 Spinal spheres for use in intervertebral fusion procedures.

* * * * *

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [A DATE WILL BE ADDED ON THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER THE FUTURE FINAL REGULATION THAT CLASSIFIES THE DEVICE INTO CLASS III IS EFFECTIVE], for any spinal sphere for use in intervertebral fusion procedures as identified in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED ON THE LAST DAY OF THE 30TH FULL CALENDAR MONTH AFTER THE FUTURE FINAL REGULATION THAT CLASSIFIES THE DEVICE INTO CLASS III IS EFFECTIVE], been found to be substantially equivalent to any spinal sphere device for use in intervertebral fusion procedures identified in paragraph (a) of this section, that was in commercial distribution before May 28, 1976. Any other spinal sphere device for use in an intervertebral fusion procedure identified in paragraph (a) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: December 9, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27139 Filed 12–14–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Chapter X

[Docket No. FINCEN–2021–0008]

Review of Bank Secrecy Act Regulations and Guidance

AGENCY: Financial Crimes Enforcement Network, Treasury.

ACTION: Request for information and comment.

SUMMARY: The Financial Crimes Enforcement Network (FinCEN) is issuing this request for information (RFI) to solicit comment on ways to streamline, modernize, and update the anti-money laundering and countering the financing of terrorism (AML/CFT) regime of the United States. In particular, FinCEN seeks comment on ways to modernize risk-based AML/CFT regulations and guidance, issued pursuant to the Bank Secrecy Act (BSA), so that they, on a continuing basis, protect U.S. national security in a cost-effective and efficient manner. This RFI also supports FinCEN's ongoing formal review of BSA regulations and guidance required pursuant to Section 6216 of the Anti-Money Laundering Act of 2020 (the AML Act). Section 6216 requires the Secretary of the Treasury (the Secretary) to solicit public comment and submit a report, in consultation with specified stakeholders, to Congress by January 1, 2022, that contains the findings and determinations that result from the formal review, including administrative and legislative recommendations.

DATES: Written comments on this RFI must be received on or before February 14, 2022.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Refer to Docket Number FINCEN–2021–0008.