DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2021–N–0310]

RIN 0910–AI32

Medical Devices; Orthopedic Devices; Classification of Spinal Spheres for Use in Intervertebral Fusion Procedures

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

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to classify spinal spheres for use in intervertebral fusion procedures (an unclassified, preamendments device) into class III for which FDA is separately proposing to require the filing of a premarket approval application (PMA). FDA has determined that general controls and special controls together are insufficient to provide reasonable assurance of safety and effectiveness for this device. FDA is publishing this proposed rule based, in part, on the recommendations of the Orthopaedic and Rehabilitation Devices Panel, regarding the classification of spinal spheres for use in intervertebral fusion procedures.

DATES: Submit either electronic or written comments on the proposed rule by March 15, 2022.

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 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–0310 for ''Medical Devices; Orthopedic Devices; Classification of 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:

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to classify spinal spheres for use in intervertebral fusion procedures (spinal spheres), which are unclassified, preamendments devices, into class III. A spinal sphere is a prescription device used to provide stabilization of a spinal segment as an adjunct to fusion. FDA currently regulates these unclassified devices as devices requiring premarket notification, with the product code NVR.

FDA initiated the classification of spinal spheres by consulting the Orthopaedic and Rehabilitation Devices Panel (the Panel). The Panel recommended that spinal spheres be classified into class III because 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 these devices present a potential unreasonable risk of illness or injury. FDA conducted its own analysis as described below and agrees with the Panel's recommendation. As such, FDA proposes to classify spinal spheres into class III. FDA is also proposing, by proposed order published elsewhere in this issue of the **Federal Register**, to require the filing of PMAs for such devices.

B. Summary of the Major Provisions of the Proposed Rule

This rule proposes to classify spinal spheres into class III. The proposed rule, if finalized, would establish the identification and classification for spinal spheres. In addition, FDA proposes that the use of spinal spheres devices be limited to prescription use.

C. Legal Authority

The Agency is proposing this classification under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301). Specifically, the relevant authority related to the proposed classification includes section 513(a) through (d) of the FD&C Act (21 U.S.C. 360c(a) through (d)), regarding device classes, classification, and panels, and section 515 (21 U.S.C. 360e), regarding PMAs.

D. Costs and Benefits

This proposed rule, if finalized, would classify spinal spheres for use in intervertebral fusion procedures (an unclassified, preamendments device) into class III for which FDA is separately proposing to require the filing of a premarket approval application. The costs of the rule include one-time costs associated with reading the proposed rule. FDA is only able to identify the costs of this proposed rule. We estimate that the present value of the costs of the rule are between $427 and $20,480, with a primary estimate of $10,453. Annualizing over a 10-year period at a discount rate of 3 percent, the costs of this proposed rule are estimated to be between $29 and $1,377, with a primary estimate of $703. Annualizing over a 10-year period at a discount rate of 7 percent, the costs of this proposed rule are estimated to be between $40 and $1,933, with a primary estimate of $987.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

TABLE 1—ABBREVIATIONS AND ACRONYMS

Abbreviation or acronym	What it means
510(k)	Premarket Notification.
CoCrMo	cobalt-chromium-molybdenum.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
MAUDE	FDA's Manufacturer and User Facility Device Experience database.
OMB	Office of Management and Budget.
PMA	Premarket Approval Application.

III. Background

A. Need for the Regulation

Currently, spinal spheres are unclassified devices subject to premarket notification (510(k)) under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Until an unclassified device type has been formally classified by regulation, marketing of new devices within this device type requires FDA clearance of a 510(k). As described below, FDA granted the first clearance for spinal spheres (K051320, September 9, 2005) based on documentation that demonstrated that these devices were substantially equivalent to devices that were in commercial distribution prior to passage of the Medical Device Amendments on May 28, 1976. Because the clinical evidence is limited, FDA is proposing to classify spinal spheres into class III, subject to PMA.

B. FDA's Current Regulatory Framework

The FD&C Act (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94–295), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: Class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under sections 501, 502, 510, 516, 518, 519, or 520 of the FD&C Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act). Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient

registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act). Class III devices are those devices for which insufficient information exists to determine that general controls (controls authorized by or under sections 501, 502, 510, 516, 518, 519, or 520 of the FD&C Act or any combination of such sections) and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Under section 513(d) of the FD&C Act, FDA refers to devices that were in commercial distribution before the 1976 amendments as ''preamendments devices.'' FDA classifies these devices after the Agency: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device (section 513(d)(1) of the FD&C Act). 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 a final regulation order under section 515(b) of the FD&C Act requiring premarket approval. FDA is also proposing, by proposed order published elsewhere in this issue of the **Federal Register**, to require the filing of PMAs for such devices.

After the enactment of the 1976 amendments, FDA undertook an effort to identify and classify all preamendments devices in accordance with section 513(d) of the FD&C Act. As part of this effort, 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 were not included in this action and were never separately classified. FDA initiated the classification of spinal spheres by holding a panel meeting on December 12, 2013, regarding the classification of spinal spheres (Ref. 1).

C. History of This Rulemaking

As described previously, 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. Spinal sphere devices, however, 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.

On December 12, 2013, FDA convened 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 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 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.

IV. Legal Authority

The Agency is proposing this classification under the authority of the FD&C Act (21 U.S.C. 301). Specifically, the relevant authority related to the proposed classification includes sections 513(a) through (d), regarding device classes, classification, and panels; and section 515, regarding PMAs.

V. Description of the Proposed Rule

We are proposing to amend subpart D of 21 CFR part 888 by adding § 888.3085 to classify spinal spheres for use in intervertebral fusion procedures in accordance with section 513(d) of the FD&C Act. This proposed rule applies to spinal spheres for use in intervertebral fusion procedures regulated under the product code NVR. This proposed rule does not apply to spinal spheres intended for use in non-fusion procedures, which are currently regulated as class III devices subject to PMA requirements.

A. Device Description

A spinal sphere for use in intervertebral fusion procedures 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) 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.

B. Risks to Health and Public Health Benefits

In evaluating the risks to health associated with use of spinal spheres, FDA considered information from the

2013 Orthopaedic and Rehabilitation Panel meeting, the adverse event reports for spinal spheres in FDA's Manufacturer and User Facility Device Experience (MAUDE) database, and published scientific literature, which is discussed in FDA's executive summary for the Panel meeting (Ref. 1). We also considered adverse event reports and literature since that time, which is consistent with the prior information that was analyzed for the Panel meeting.

FDA's review of the information in the MAUDE database, as presented to the Panel, resulted in the identification of 21 unique Medical Device Reports (MDRs) on spinal sphere devices. Of this total, 18 MDRs 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, for the purposes of the Panel, 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.

At the Panel, FDA identified the following risks to health associated with spinal spheres that could result from device-related adverse events, including implant breakage during implantation, device migration and/or subsidence, removal/revision, pain, and neurological impairment. The Panel agreed with the risks to health and emphasized that there would likely be a significantly higher risk of revision or clinical failure as compared to standard intervertebral body fusion devices. Furthermore, the Panel noted that these risks to health may arise from mechanical instability associated with placement of a spherical implant inserted between the parallel vertebral endplates. Additionally, the Panel acknowledged that the risks to health identified for intervertebral body fusion devices would also apply to spinal spheres (Ref. 1). These devices are similar in terms of materials, placement, and insertion, and therefore spheres would also carry similar risks as those already identified for intervertebral body fusion devices. The risks to health associated with use of intervertebral body fusion devices that contain bone grafting material identified during their reclassification were infection, adverse tissue reaction, pain and loss of function, soft tissue injury, vertebral endplate injury, reoperation, and pseudarthrosis (*i.e.,* non-union) (72 FR 32170, June 12, 2007).

FDA agrees with the Panel's recommendations to incorporate the risks to health associated with intervertebral body fusion devices into the list of risks to health FDA identified as associated with spinal spheres to more completely capture the risks to health associated with such devices. FDA notes that the risk of vertebral endplate injury as described in the risks associated with intervertebral body fusion devices also encompasses the risk of subsidence; therefore, we are not listing subsidence as a unique risk to health for spinal spheres. Based on this information, FDA has identified and proposes the following risks to health for spinal spheres:

(1) *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.

(2) *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.

(3) *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.

(4) *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.

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

(6) *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.

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

(8) *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.

(9) *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.

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. As described above, however, FDA is not aware of evidence supporting the stated benefit of spinal spheres for use in fusion procedures.

C. Proposed Classification and FDA's Findings

Based on FDA's experience with spinal spheres, the Panel's recommendations, and other available

information, FDA is proposing to classify spinal spheres for use in intervertebral fusion procedures into class III. FDA is proposing this classification because FDA believes that insufficient information exists to determine that general controls and special controls would provide reasonable assurance of safety and effectiveness for such devices and, based upon assessment of benefits and risks, these devices present a potential unreasonable risk of illness or injury. Elsewhere in this issue of the **Federal Register**, FDA is proposing through a proposed order to require the filing of a PMA under section 515(b) of the FD&C Act. The proposed order will only be finalized if and when FDA finalizes this proposed rule classifying spinal spheres in class III.

VI. Proposed Effective/Compliance Dates

FDA proposes that any final rule, based on this proposed rule, become effective 30 days after its date of publication in the **Federal Register**.

If this proposed rule and related proposed order to require the filing of a PMA are finalized, spinal spheres for use in intervertebral fusion procedures are considered adulterated if a PMA is not filed with FDA within 30 months after the classification of the device into class III, and commercial distribution of the product must cease (see section 501(f)(1)(2)(B) of the FD&C Act). However, the product may be distributed for investigational use only, if the requirements of the investigational device exemptions regulations in 21 CFR part 812 are met.

VII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the estimated costs imposed on any affected firm are very low, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This proposed rule, if finalized would classify spinal spheres for use in intervertebral fusion procedures (an unclassified, preamendments device) into class III for which FDA is separately proposing to require the filing of a PMA.

The costs of the proposed rule are summarized in table 2; we did not quantify benefits for this proposed rule. The costs of the rule include one-time costs associated with reading the proposed rule. The present value of the costs of the rule are estimated to be between $427 and $20,480, with a primary estimate of $10,453. The annualized value of the primary estimate of costs over 10 years at a 3 percent discount rate is approximately $703. The annualized value of the primary estimate of costs over 10 years at a 7 percent discount rate is approximately $987.

TABLE 2—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Benefits:							
Annualized					7	10	
Monetized $millions/year					3	10	
Annualized					7	10	
Quantified					3	10	
Qualitative							
Costs:							
Annualized	$0.00099	$0.00004	$0.00193	2019	7	10	
Monetized $millions/year	0.00070	0.00003	0.00138	2019	3	10	
Annualized					7	10	
Quantified					3	10	
Qualitative						10	
Transfers:							
Federal					7	10	
Annualized					3	10	
Monetized $millions/year						10	
From/To	From:			To:			
Other					7	10	
Annualized					3		
Monetized $millions/year						10	

TABLE 2—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
From/To	From:			To:			
Effects: State, Local or Tribal Government: None. Small Business: Costs would not exceed 0.002 percent of average small firm annual revenues. Wages: None. Growth: None.							

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 3) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VIII. 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.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. 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/7993/20170405192244/https:/www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm352525.htm.*

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.

3. * FDA's full preliminary analysis of economic impacts is available in the Docket No. FDA–2021–N–0310 for this proposed rule and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

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, 360l, 371.

■ 2. Add § 888.3085 to subpart D to read as follows:

§ 888.3085 Spinal spheres for use in intervertebral fusion procedures.

(a) *Identification.* 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.

(b) *Classification.* Class III.

Dated: December 9, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27137 Filed 12–14–21; 8:45 am]

BILLING CODE 4164–01–P