This document is scheduled to be published in the Federal Register on 03/30/2023 and available online at **federalregister.gov/d/2023-06566**, and on **govinfo.gov**

4164-01-P

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, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing a final rule to classify spinal spheres for use in intervertebral fusion procedures (an unclassified, preamendments device) into class III for which FDA is separately requiring 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.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this final rule, 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 Final Rule

FDA is classifying 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. The classification of spinal spheres was consistent with the recommendation of the Orthopaedic and Rehabilitation Devices Panel meeting held on December 12, 2013 (the Panel) and our consideration and analysis of public comments received following the publication of the proposed rule. FDA is also, by final order published elsewhere in this issue of the *Federal Register*, requiring the filing of PMAs for such devices.

B. Summary of the Major Provisions of the Final Rule

This rule establishes the identification and classification for spinal spheres as class III devices. In addition, the use of spinal spheres devices is limited to prescription use.

C. Legal Authority

The Agency is issuing this rule 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 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 rule classifies spinal spheres for use in intervertebral fusion procedures (an unclassified, preamendments device) into class III for which FDA is separately requiring the filing of a PMA. The costs of the rule include one-time costs associated with reading the rule. FDA is only able to identify the costs of this rule. We estimate that the present value of the costs of the rule are between $335 and $16,093, with a primary estimate of $8,214. Annualizing over a 10-year period at a discount rate of 3 percent, the costs of this rule are estimated to be between $23 and $1,082, with a primary estimate of $552. Annualizing over a 10-year period at a

discount rate of 7 percent, the costs of this rule are estimated to be between $32 and $1,519, with a primary estimate of $775.

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
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
PMA	Premarket Approval Application

III. Background

A. History of This Rulemaking

In the *Federal Register* of December 15, 2021 (86 FR 71191) FDA issued a proposed rule to classify spinal spheres for use in intervertebral fusion procedures (an unclassified, preamendments device) into class III for which FDA requires the filing of a PMA and invited interested persons to comment on the proposed regulation by March 15, 2022. These proposals were consistent with feedback received from the Panel meeting held on December 12, 2013.

B. Summary of the Comments to the Proposed Rule

FDA received two comments on the proposed rule--one from academia and another from an anonymous source. The comments were supportive of the classification of spinal spheres into class III as stated in the proposed rule and no changes were made in response to the comments in the final rule.

IV. Legal Authority

We are issuing this final rule under the authority of the FD&C Act (21 U.S.C. 301). Specifically, the relevant authority related to the classification includes sections 513(a) through (d), regarding device classes, classification, and panels; and section 515, regarding PMAs.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received a few comment letters on the proposed rule by the close of the comment period. We received comments from academia and from an anonymous source. We describe and respond to the comments in section V.B of this document.

B. Description of Comments and FDA Response

Both commenters supported FDA's proposed classification of spinal spheres for use in intervertebral fusion procedures (an unclassified, preamendments device) into class III for which FDA would require the filing of a PMA. The academic commenter agreed with FDA's assessment that this device type poses "a potential unreasonable risk of illness or injury." The commenter described negative patient outcomes as reported in the literature and noted that classification of these devices into class III will safeguard patients undergoing spine surgery from a potentially devastating process and prevent the sale of a risky, unproven device.

Additionally, another commenter stated that strong evidence is necessary to demonstrate the medical benefits of this device type prior to subjecting patients to the risks associated with these devices.

We agree with both commenters supporting classification of spinal spheres to class III because there is 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 an unreasonable risk of illness or injury. As described in the preamble to the proposed rule, the risks to health from spinal spheres include 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 is not making any changes in the final rule in response to these comments.

In the final rule, we are revising the section number from § 888.3085 (21 CFR 888.3085) to 21 CFR 888.3083, because a De Novo was previously granted under § 888.3085. No other substantive changes were made to the regulation.

VI. Effective/Compliance Dates

This final rule will become effective 30 days after its date of publication in the *Federal Register*.

After this rule and related order to require the filing of a PMA are effective, spinal spheres for use in intervertebral fusion procedures will be 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)(2)(B) of the FD&C Act (21 U.S.C. 351(f)(2)(B))). 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. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final 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 final 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 certify that the final 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 issuing "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 $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This final rule classifies spinal spheres for use in intervertebral fusion procedures (an unclassified, preamendments device) into class III for which FDA is separately issuing an order to require the filing of a PMA.

The costs of the final rule are summarized in table 2; we did not quantify benefits for this rule. The costs of the rule include one-time costs associated with reading and understanding the rule. The present value of the costs of the rule are estimated to be between $335 and $16,093, with a primary estimate of $8,214. The annualized value of the primary estimate of costs over 10 years at a 3 percent discount rate is approximately $552. The annualized value of the primary estimate of costs over 10 years at a 7 percent discount rate is approximately $775.

Table 2.--Summary of Benefits, Costs, and Distributional Effects of the Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year					7%	10 Years	
						3%	10 Years	
	Annualized Quantified					7%	10 Years	
						3%	10 Years	
	Qualitative							
Costs	Annualized Monetized $millions/year	$0.0008	$0.00003	$0.002	2021	7%	10 Years	
		$0.0006	$0.00002	$0.001	2021	3%	10 Years	
	Annualized Quantified					7%	10 Years	
						3%	10 Years	
	Qualitative						10 Years	
Transfers	Federal Annualized Monetized $millions/year					7%	10 Years	
						3%	10 Years	
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%	10 Years	
						3%	10 Years	
	From/To	From:			To:			

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
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 Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) 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

This final 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 final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the 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 rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that would have substantial

direct effects 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

XII. Reference

The following reference is on display at the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at https://www.regulations.gov. 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. FDA's full analysis of economic impacts is available in the Docket No. FDA-2021-N-0310 for this rule and at https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.

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 § 888.3083 to subpart D to read as follows:

§ 888.3083 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: March 17, 2023

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2023-06566 Filed: 3/29/2023 8:45 am; Publication Date: 3/30/2023]