Country	Entity	License requirement	License review policy	Federal Register citation
*	* * *	*	* *	*
RUSSIA	* * *	*	* *	*
	Aviatech Supply Ltd., a.k.a., the following two aliases: -Aviatech; *and* -Aviatechexport Ltd. 630123, Aeroport St. Build.1A, 3rd Floor, Novosibirsk, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	88 FR [INSERT FR PAGE NUMBER] 3/30/2023
	Aviazapchast PLC, 48, Ivana Franko Street, Moscow, 121351, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	88 FR [INSERT FR PAGE NUMBER] 3/30/2023.
	* *	*	* *	
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Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2023–06663 Filed 3–28–23; 4:15 pm]

BILLING CODE 3510–33–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

General Rules and Regulations, Securities Exchange Act of 1934

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 17 of the Code of Federal Regulations, Part 240, revised as of April 1, 2022, in section 240.13e–100, reinstate the paragraphs at the end of the section following ''Item 16. Exhibits'' to read as follows:

§ 240.13e–100 Schedule 13E–3, Transaction statement under section 13(e) of the Securities Exchange Act of 1934 and Rule 13e–3 (§ 240.13e–3) thereunder.

* * * * *

Signature. After due inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

(Signature)

(Name and title)

(Date)

Instruction to Signature: The statement must be signed by the filing person or that person's authorized representative. If the statement is signed on behalf of a person by an authorized representative (other than an executive officer of a corporation or general partner of a partnership), evidence of the representative's authority to sign on behalf of the person must be filed with the statement. The name and any title of each person who signs the statement must be typed or printed beneath the signature. See § 240.12b–11 with respect to signature requirements.

[FR Doc. 2023–06701 Filed 3–29–23; 8:45 am]

BILLING CODE 0099–10–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 May 1, 2023.

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:

Table of Contents

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 (years)	
Benefits:							
Annualized Monetized $millions/year					7	10	
					3	10	
Annualized Quantified					7	10	
					3	10	
Qualitative							
Costs:							
Annualized Monetized $millions/year	$0.0008	$0.00003	$0.002	2021	7	10	
	0.0006	0.00002	0.001	2021	3	10	
Annualized Quantified					7	10	
					3	10	
Qualitative						10	
Transfers:							
Federal Annualized Monetized $millions/year					7	10	
					3	10	
From/To	From:			To:			
Other Annualized Monetized $millions/year					7	10	
					3	10	
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 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 3–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–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, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing a final order to require the filing of a premarket approval application (PMA) for spinal spheres for use in intervertebral fusion procedures, an unclassified, preamendments device following the classification of the device into class III.

DATES: This order is effective on May 1, 2023. 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 IX for the effective date of the final order. See section VI of this document for more information about submitting a PMA.

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 Federal Food, Drug, and Cosmetic Act (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 of the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), on May 28, 1976, (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 a final 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