DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

Docket No. FDA-2021-N-0310

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Economics and Analysis
Office of Policy, Legislation, and International Affairs
Office of the Commissioner

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I. Introduction and Summary

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 $156 million, using the most current (2019) 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 premarket approval (PMA) application.

The costs of the proposed rule are summarized in Table 1; 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 1: Summary of Benefits, Costs and Distributional Effects of Proposed 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	$0.00099	$0.00004	$0.00193	2019	7%	10 Years	
		$0.00070	$0.00003	$0.00138	2019	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:			
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							

II. Preliminary Economic Analysis of Impacts

A. Background

FDA is proposing to classify spinal spheres for use in intervertebral fusion procedures (spinal spheres), which are unclassified, preamendments devices, into class III devices. 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 Medical Device Amendments of 1976 amended the Food, Drug, and Cosmetic Act (FD&C Act) to define and create a risk-based classification system for medical devices. FDA refers to devices that were commercially distributed prior to May 28, 1976, the date of enactment

of the Medical Device Amendments of 1976, as "preamendments devices." Section 513(d)(1) of the FD&C Act allows FDA to classify preamendments devices once we: (1) receive a recommendation from a device classification panel (an FDA advisory committee); (2) publish the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publish a final regulation classifying the device. FDA initiated the classification of spinal spheres by consulting the Orthopaedic and Rehabilitation Devices Panel (the Panel). FDA initiated the classification of spinal spheres by holding a panel meeting on December 12, 2013, regarding the classification of spinal spheres (Ref. 1). The Panel recommended that spinal spheres be classified into class III because insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of safety and effectiveness and these devices present a potential unreasonable risk of illness or injury.

B. Market Failure Requiring Federal Regulatory Action

After the enactment of the Medical Device Amendments of 1976, FDA began to identify and classify all preamendments devices. We have determined that the unclassified spinal sphere devices should be classified as Class III medical devices. This proposed rule is in-line with FDA's efforts to classify all preamendments devices. Thus, regulatory action is necessary to classify spinal sphere devices as class III devices.

C. Purpose of the Proposed Rule

The purpose of this proposed rule is to classify spinal sphere devices into class III. FDA has determined that general controls and special controls together are insufficient to provide reasonable assurance of safety and effectiveness for this device.

D. Baseline Conditions

The impact of the rule is estimated relative to the baseline, which is the state of the world in absence of regulatory action. This proposed rule, if finalized, has the potential to affect the market for spinal sphere devices for use in intervertebral fusion devices. Currently, four firms have obtained six 510(k) clearances to market spinal sphere devices. However, due to the widespread adoption of intervertebral body fusion devices ("interbody cages"), spinal sphere devices, intended for use in fusion procedures, are no longer used.[1] Furthermore, FDA has

[1] 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

communicated with the four firms with existing 510(k) approvals and have confirmed that these firms are not currently marketing spinal sphere devices. Overall, we do not expect that any firm with an existing 510(k) approval would choose to market the device in the absence of the rule. Similarly, we do not expect that any other firms without an existing 510(k) approval would choose to market a spinal sphere device irrespective of the status of this rule.

E. Costs of the Proposed Rule

1. Cost to read and understand the rule

We expect that firms affected by this rule will incur costs to read and understand the rule. Table 2 presents the values used to calculate the cost of reading the rule as well as a breakdown of costs reflecting the range of estimates of the number of firms expected to read the rule. The proposed rule has approximately 5,000 words.

Table 2. Values Used to Calculate Costs of Reading Proposed Rule

	Low Estimate	Primary Estimate	High Estimate
Assumed Reading Speed (WPM)	228	228	228
Words in Proposed Rule	5000	5000	5000
Hours to read Rule	0.37	0.37	0.37
Employees Reading Rule	2	2	2
Wage	$145.92	$145.92	$145.92
Per Firm Cost	$107	$107	$107
Firms	4	98	192
Costs	$426.67	$10,453	$20,480

Consistent with Guidelines from the Department of Health and Human Services (Ref. 2), we assume that the mean reading speed of regulation reviewers is 228 words per minute (Ref. 3). The overall burden in hours (per reader) to read the rule is approximately 0.37 hours. We assume that each firm taking the time to read and understand the rule will assign the task to two lawyers. As reported in Table 2, the fully-loaded hourly wage for lawyers in this industry is $145.92. Each firm would incur a cost of approximately $107 to read the rule.

allow for the packing of graft material, facilitating bone growth into and through the device.

The total industry costs of reading and understanding the rule depend on the number of firms which choose to read the rule. As this number is not certain we construct a range to estimate these costs. At the low-end, we expect that only the four firms with existing spinal sphere 510(k) clearances will incur costs associated with reading and understanding the rule. At the high-end, we expect that firms with 510(k) clearances for other spinal fusion devices would also take the time to read and understand the rule. The high-end estimate of the number of firms reading the rule include the four firms with existing 510(k) clearances for spinal sphere devices plus firms with existing 510(k) clearances for Intervertebral Fusion Device with Bone Graft, Lumbar (product code: MAX) plus Intervertebral Fusion Device with Integrated Fixation, Lumbar (product code: OVD). If all firms with existing 510(k) clearances for these devices took the time to read and understand the rule, our high-end estimate of the number of firms is 192. As reported in Table 2, the low estimate of total industry costs associated with reading and understanding the rule is approximately $427. The high estimate of the costs associated with reading and understanding the rule is $20,480. The primary estimate of the costs associated with reading and understanding the rule is approximately $10,453.

The primary estimate of the annualized costs associated with reading and understanding the rule are presented in Table 3.

Table 3. Primary Estimates of the Total One-Time Cost to Read and Understand the Proposed Rule ($millions)

Present Value (3%)	$0.0105
Present Value (7%)	$0.0105
Annualized Value (3%)	$0.0007
Annualized Value (7%)	$0.0010

2. Other costs

As mentioned in the section describing baseline conditions, FDA subject matter experts have advised us that spinal sphere devices are no longer being used. Furthermore, communications with industry have confirmed that firms with existing 510(k) clearances are no longer marketing these devices. However, we acknowledge that this rule would impose costs on industry should any firm choose to market a spinal sphere device in the future.

Spinal sphere 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 (see section 513(i) of the FD&C Act). If the proposed order accompanying this proposed rule is 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 or 90 days of the date of the issuance of an action under 515(b) requiring a PMA, whichever is later, and commercial distribution of the product must cease. The cost to industry would be the difference in costs between the 510(k) and PMA approval pathway.

Relative to the 510(k) clearance process, the PMA pathway is costlier for both the applicant and the FDA. The costs imposed on FDA would include an increase in the number of hours required to review a PMA application relative to a 510(k) application. If spinal sphere devices are marketed in the future, industry would also incur significant costs because the cost of developing a device subject to the PMA approval pathway is generally significantly higher than devices which require premarket notification. Devices which require a PMA are subject to different labeling and site inspection requirements. Furthermore, devices which require a PMA generally require clinical trials, whereas only a fraction of 510(k) devices require clinical trials. Finally, the regulatory submissions necessary for devices which require a PMA are generally costlier than the regulatory submissions required for 510(k) devices. We also note that although user fees are considered a transfer, the user fee associated with a PMA submission would be higher than that for a 510(k) submission. While these PMA-related costs are associated with the proposed order, rather than this proposed rule, we are discussing them here because this rulemaking is required prior to issuing the proposed order.

We request comments on our assumptions that: 1) no spinal sphere devices are currently being marketed; 2) industry will not introduce new spinal sphere devices after the publication of this rule, and; 3) in the absence of this proposed rule, industry would not have introduced a new spinal sphere device onto the market. If our assumptions regarding the current and future state of the spinal sphere device market are incorrect, we further request comment on the costs associated with introducing a spinal sphere device to the market utilizing the PMA pathway relative to the 510(k).

F. Analysis of Regulatory Alternatives to the Proposed Rule

Solely for the purpose of this economic analysis, we have identified regulatory alternatives to the proposed rule. One alternative would be to regulate spinal spheres as either a

class I or a class II device. Although industry would still incur the costs associated with reading and understanding the rule, it could result in lower compliance costs should firms choose to market spinal sphere devices in the future. This alternative is not intended to suggest that a class I or class II classification could be appropriate under the relevant statutory standards.

Another alternative would be delaying the implementation of the rule by one year. Moving the compliance date back could shift the one-time costs of reading the rule further into the future. If we were to delay the implementation of the rule by one year, using a 3% discount rate, the net present value of the costs associated with rule is estimated to be reduced by between $12.43 and $596.50 with a primary estimate of $304.47. Using a 7% discount rate, a one-year delay in the implementation of the rule would result in a reduction of costs with a net present value of between $27.91 and $1,339.81 with a primary estimate of $683.86.

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the estimated costs imposed by the rule would not exceed 0.002 percent of the annual revenues of the average small firm in this industry, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

To assess the rule's economic impact on small entities, we compare the rule-related costs to each establishment's revenues.

A. Description and Number of Affected Small Entities

Firms producing spinal sphere devices are classified under NAICS subsector 339112: Surgical and medical instrument manufacturing. The Small Business Administration defines a small business in this sector as those having fewer than 500 employees (Ref. 4). As seen in Table 4, 1,096 (or approximately 92%) of the firms classified under NAICS 339112 are defined as a small firm. Only one of the four firms with existing 510(k) clearances is considered a small business.

Table 4. Estimated Percentage of Small Firms among Firms with Employees

NAICS	Description of NAICS Category	Number of Firms	Number of Firms considered small by SBA Definition	Percentage of Small Firms (%)
339112	Surgical and Medical Instrument Manufacturing	1,188	1,096	92%

B. Description of the Potential Impacts of the Rule on Small Entities

We use detailed data from the 2012 Statistics of U.S. Businesses on U.S. 6-digit NAICS detailed employment sizes to analyze the potential impacts of this proposed rule on small entities (Ref. 5). This detailed data allows us to match the SBA size standards more closely to the Census employment categories.

The per-firm costs associated with reading and understanding the rule is approximately $107. As seen in Table 5, the average annual revenues of small firms in the surgical and medical instrument manufacturing industry is approximately $6.7 million.

Table 5. Compliance costs and costs as percentage of annual receipts

	All firms	Small Firms
Average Annual Receipts	$35,303,077	$6,671,337
Costs associated with the rule	$107	$107
Costs as a percentage of Annual Receipts	0.00030%	0.00160%

As shown in Table 5, the costs associated with the rule are estimated to fall below 0.002 percent of the annual revenues of small firms in this industry. Therefore, we certify that this proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities.

IV. References

1. U.S. Food and Drug Administration. Orthopaedic and Rehabilitation Devices Panel – Classification of Spinal Sphere Devices Meeting – December 12, 2013 2013 [Available from: https://wayback.archive-it.org/7993/20170405192244/https:/www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm352525.htm.
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