DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Medical Devices; Orthopedic Devices; Classification of Posterior Cervical Screw Systems

[Docket No. FDA-2015-N-3785]

Final Regulatory Impact Analysis

Final Regulatory Flexibility Analysis

Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." 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. We have identified sixteen manufacturers that could be considered small entities. Two of these manufacturers each produce two devices covered by this rule. Because our final regulatory impact analysis finds that more small entities will incur relatively low costs to comply with the final rule than estimated in our preliminary regulatory impact analysis, we find 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 $150 million, using the most current (2017) 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 will classify posterior cervical screw systems as class II devices with special controls. Although these devices are currently unclassified, manufacturers are subject to premarket requirements like class II devices, with manufacturers receiving clearance to market the device via a 510(k) submission without a PMA requirement. We have concluded that special controls in addition to general controls are sufficient to reasonably ensure the safety and effectiveness of these devices and that these devices may be classified as class II (special controls).

The final rule's costs are summarized in Table 1; we did not quantify benefits for this rule. Costs are calculated as the one-time costs of relabeling affected devices to comply with the rule and costs associated with reading and understanding the rule. The total estimated one-time costs of this rule are $503,700. The present value of these costs is $503,700 because they are one-time costs that are expected to occur in the first year. The annualized cost of this rule over ten years is $62,777 at a 7 percent discount rate and $52,853 at a 3 percent discount rate. The annualized cost of this rule over an infinite time horizon is $32,952 at a 7 percent discount rate and $14,671 at a 3 percent discount rate.

Table 1 provides the Regulatory Information Service Center and Office of Information and Regulatory Affairs Combined Information System accounting information for this analysis.

Table 1. --Summary of Benefits, Costs and Distributional Effects of Final Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year				2016	7%	10 years	
					2016	3%	10 years	
	Annualized Quantified				2016	7%	10 years	
					2016	3%	10 years	
	Qualitative							
Costs	Annualized Monetized $millions/year	0.063			2016	7%	10 years	
		0.053			2016	3%	10 years	
	Annualized Quantified				2016	7%	10 years	
					2016	3%	10 years	
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year				2016	7%	10 years	
					2016	3%	10 years	
		From:			To:			
	Other Annualized Monetized $millions/year				2016	7%	10 years	
					2016	3%	10 years	
		From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages: Growth:							

In line with Executive Order 13771, in Table 2, we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these costs, we consider this final rule a regulatory action under Executive Order 13771.

Table 2. EO 13771 Summary Table (in $ Millions 2016 dollars, over an infinite time horizon)

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	0.5			0.5		
Present Value of Cost Savings						
Present Value of Net Costs	**0.5**			**0.5**		
Annualized Costs	0.033			0.015		
Annualized Cost Savings						

Annualized Net Costs	**0.033**			**0.015**		

C. Comments on the Preliminary Regulatory Impact Analysis and Our Responses

Comment 1) A commenter suggests that, within the Economic Analysis section of the proposed rule, it is unclear whether the required addition of precautions to the device labeling would require manufacturers to submit a new 510(k) for devices already on the market, and recommends that we explicitly state that such a submission would not be required to revise the labeling for devices already on the market to add the precautions.

Response 1) FDA disagrees with this comment. As in the proposed rule we explicitly state that, "It is not expected that manufacturers of devices already on the market would need to submit new 510(k) notifications, 510(k) amendments, or add-to-files to demonstrate conformance with the special controls." We retain this language in our analysis in this document. We expect that firms will not submit a new 510(k) for the addition of the specified precaution statement.

Comment 2) A commenter noted that in the Economics Analysis, the words "major label change" is used to describe the addition of the new precaution. The commenter did not make an explicit suggestion regarding the use of these words, though we inferred this language may cause confusion.

Response 2) The labeling cost model we used to estimate the cost of a label change categorizes the scope of the change as either minor, major, or extensive. We selected the type of labeling change that most closely matches the required labeling change. To reduce potential confusion, we removed language referring to the scope as being a "major label change."

II. Final Regulatory Impact Analysis

A. Background

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. We refer to medical devices in commercial distribution before the enactment of the law as "preamendments devices." Posterior cervical screw systems are preamendments devices and thus not classified as class I, class II, or class III devices. Although these devices are currently unclassified, manufacturers are subject to premarket requirements like class II devices, with manufacturers receiving clearance to market via a 510(k) submission without a PMA requirement.

Section 513(d)(1) of the FD&C Act allows us to classify preamendments devices once we follow the procedures outline in this section, which includes publishing a final regulation to classify the device. This final rule will classify these devices into class II (special controls).

B. Market Failure Requiring Federal Regulatory Action

After the enactment of the Medical Device Amendments of 1976, FDA commenced to identify and classify all preamendments devices. We have determined that the unclassified posterior cervical screw systems should be classified as Class II medical devices with special controls. The final rule is in-line with FDA's efforts to classify all preamendments devices. Thus, regulatory action is necessary to classify posterior cervical screw systems as class II devices.

C. Purpose of the Rule

Through this final rulemaking, we will classify posterior cervical screw systems (product code NKG) into class II. This decision was based upon the recommendation of the Orthopaedic and Rehabilitation Devices Panel, and FDA's consideration and analysis of the public comments received following the publication of the proposed rule. FDA believes that the special controls established and imposed by this final rule, together with the general controls, will provide a reasonable assurance of safety and effectiveness of the device.

D. Baseline Conditions

This final rule is expected to affect the posterior cervical screw system market. The rule's impact is estimated relative to the baseline, which is the state of the world in absence of the final regulatory action. To establish the baseline market, we determine the number of listed posterior cervical screw systems and the number of manufacturers of these systems. We have identified thirty-eight posterior cervical screw systems currently marketed and thirty-two manufacturers of those devices.

E. Costs

FDA's Medical Device Registration and Listing database identifies 32 manufacturers of 38 posterior cervical screw systems. Representatives from these manufacturers will spend time reading and understanding the final rule. The length of the rule is approximately 5,000 words; assuming a reading speed of 200 words per minute, it will take someone approximately 30 minutes to read the rule. The average wage rate for a lawyer in the medical equipment and supplies manufacturing industry is $78.69. We double this rate to account for overhead costs. This results in an hourly labor cost of $157.38. The estimated labor costs from reading and understanding this rule are approximately $2,518 (=$157.38 x 32 manufacturers x 0.5 hours).

Manufacturers of these devices also will revise current labeling to reflect requirements of the final rule. Any manufacturers seeking new marketing authorization of posterior cervical screw systems will not incur additional labeling costs because of this rule because we already require labeling as part of the 510(k) submissions for medical devices with special controls. However, any manufacturer of currently marketed devices who seeks marketing authorization for their devices as posterior cervical screw systems will incur similar costs. We do not have an estimate of the number of products this will likely affect. Using our labeling cost model, we estimate one-time cost of the labeling change for currently marketed posterior cervical screw systems equals $13,189 per product for an estimated total one-time cost of $501,182 (= 38 × $13,189).

The total estimated one-time costs of this rule are $503,700 (=$2,518 + $501,182). The present value of these costs equals $503,700 because they are one-time costs that are expected to occur in the first year. The annualized cost of this rule over ten years is $62,777 at a 7 percent discount rate and $52,853 at a 3 percent discount rate. The annualized cost of this rule over an infinite time horizon is $32,952 at a 7 percent discount rate and $14,671 at a 3 percent discount rate. The final rule will require that manufacturers who wish to market these devices submit 510(k) premarket notifications and comply with the special controls.

It is not expected that manufacturers of devices already on the market would need to submit new 510(k) notifications, 510(k) amendments, or add-to-files to demonstrate conformance with the special controls. Hence, the final rule would not result in any significant change in how manufacturers prepare 510(k) submissions for the affected devices or in how we would review the submissions. Because our formal classification of the affected devices as class

II medical devices follows current Agency and industry practice we conclude that the final rule will not impose a significant additional regulatory burden.

F. Alternatives

Rules that classify a preamendments device can classify the device as a class I, class II, class III device. This rule classifies posterior cervical screw systems as class II devices. Thus, the alternatives to this rule would be to classify posterior cervical screw systems as either class I or class II devices.

As noted in the preamble, Class I devices are lower risk devices for which the general controls are sufficient to provide reasonable assurance of safety and effectiveness. Posterior cervical screw systems are implanted devices and therefore the general controls of class I devices are insufficient to reduce the potential risks associated with these devices.

Also noted in the preamble, Class III devices are the highest risk devices. For devices in this class, insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and the devices are used 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. The Orthopaedic and Rehabilitation Devices Panel recommended classifying posterior cervical screw systems as class II devices. From this recommendation by the panel, we conclude that sufficient information exists to determine that general and special controls are a reasonable assurance of safety and effectiveness for these implanted devices.

III. Small Entity Effects

In this final rule, small entities will bear relabeling costs and costs associated with reading and understanding the rule. The expected cost to small firms of complying with this rule ranges from $39,724 for firms with one device to $79,291 for firms with two devices. The costs of the changes, along with the small number of firms affected, implies that this burden would not have a significant impact on a substantial number of small entities. This analysis, together with other relevant sections of this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

The final rule would impact entities that manufacture posterior cervical screw systems. The FDA Establishment Registration & Device Listing database indicates that there are 32 entities that manufacture these devices. The Small Business Administration (SBA) defines entities classified in North American Industry Classification System (NAICS) code 339112 "Surgical and Medical Instrument Manufacturing" to be small if they employ fewer than 1000 workers. Using internal information and information from Dun & Bradstreet, we identified sixteen manufacturers that could be considered small firms. The manufacturers identified as small firms produce eighteen of the thirty-eight listed posterior cervical screw systems; two small firms each produce two posterior cervical screw systems.

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

We estimate that most small firms will incur cost of $13,346 (=$157+$13,346) for reading and understanding the rule and relabeling one device. It is expected that two small firms will incur costs of $26,535 (=$157+$13,346+$13,346) for reading and understanding the rule and relabeling two devices. We compare the cost of these rules to information on "Surgical and

Medical Instrument Manufacturing" from the 2012 Economic Census, the most recent Economic Census available. Manufacturing of posterior cervical screw systems is a subset of the "Surgical and Medical Instrument Manufacturing" industry, though we assume firm level averages by employment size are similar across the industry. Table 3 presents information on number of establishments, payroll and sales by employment size for the industry, not just the posterior cervical screw system sector.

Table 3. Surgical and Medical Instrument Manufacturing industry, number of establishments, annual payroll, and total value of shipments and receipts for services, by establishment size

Employment size of establishments	Number of establishments	Annual payroll ($1,000)	Total value of shipments and receipts for services ($1,000)
0 to 4 employees	468	n/a	n/a
5 to 9 employees	167	72,595	n/a
10 to 19 employees	152	139,141	n/a
20 to 49 employees	175	341,188	n/a
50 to 99 employees	121	494,566	1,804,781
100 to 249 employees	139	1,290,764	6,192,086
250 to 499 employees	73	1,544,023	11,129,373
500 to 999 employees	28	1,206,873	6,872,926
1,000 to 2,499 employees	13	1,515,937	8,680,520
2,500 employees or more	1	n/a	n/a
All establishments	1,337	6,758,871	37,675,583

The average annual total payroll for firms with 5 to 999 employees is $5,952,220. We are using annual total payroll because we have more information on payroll than we have information on value of shipments. We assume payroll would be less than revenue. Therefore, using payroll as a proxy for revenue would provide an overestimate of the impact of the cost of the rule on small entities. For firms that produce one posterior cervical screw system, we overestimate that the cost of the rule is approximately 0.2% of revenue (=$13,346/$5,952,220).

For firms that produce two posterior cervical screw systems, we overestimate that the cost of the rule is approximately 0.4% of revenue (=$26,535/$5,952,220). Using value of shipments information, the average annual sales for firms with 50 to 999 employees is $72,019,850. Using this value as a proxy for the average revenue for small firms that produce posterior cervical screw systems, we estimate that the cost of this rule is approximately 0.02% of revenue (=$13,346/$72,019,850) for firms that produce one posterior cervical screw system and 0.04% of revenue (=$26,535/$72,019,850) for firms that produce two of these devices.

Because of the relatively low cost of compliance with this rule, we find that the final rule will not have a significant economic impact on a substantial number of small entities.