■ 2. Section 866.3045 is added to subpart D to read as follows:

§ 866.3045 In vitro diagnostic device for *Bacillus* spp. detection.

(a) *Identification.* An in vitro diagnostic device for *Bacillus* species (spp.) detection is a prescription device used to detect and differentiate among *Bacillus* spp. and presumptively identify *B. anthracis* and other *Bacillus* spp. from cultured isolates or clinical specimens as an aid in the diagnosis of anthrax and other diseases caused by *Bacillus* spp. This device may consist of *Bacillus* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to presumptively identify bacillus-like organisms in clinical specimens; bacteriophage used for differentiating *B. anthracis* from other *Bacillus* spp. based on susceptibility to lysis by the phage; or antigens used to identify antibodies to *B. anthracis* (anti-toxin and anti-capsular) in serum. Bacillus infections include anthrax (cutaneous, inhalational, or gastrointestinal) caused by *B. anthracis,* and gastrointestinal disease and non-gastrointestinal infections caused by *B. cereus.*

(b) *Classification.* Class II (special controls). The special controls are set forth in FDA's special controls guideline document entitled ''In Vitro Diagnostic Devices for *Bacillus* spp. Detection; Class II Special Controls Guideline for Industry and Food and Drug Administration Staff.'' For availability of the guideline document, see § 866.1(e).

(c) *Restriction on Distribution.* The distribution of these devices is limited to laboratories that follow public health guidelines that address appropriate biosafety conditions, interpretation of test results, and coordination of findings with public health authorities.

(d) *Restriction on Use.* The use of this device is restricted to prescription use and must comply with the following:

(1) The device must be in the possession of:

(i)(A) A person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(B) A practitioner, such as a physician, licensed by law to use or order the use of such device; and

(ii) The device must be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(2) The label of the device shall bear the statement ''Caution: Federal law restricts this device to sale by or on the order of a ____'', the blank to be filled with the word ''physician'' or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device.

(3) Any labeling, as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act, whether or not it is on or within a package from which the device is to be dispensed, distributed by, or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder-piece labeling which calls attention to the name of the device but does not include indications or other use information.

(4) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

Dated: March 22, 2019.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2019–06026 Filed 3–29–19; 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–2015–N–3785]

RIN 0910–AI00

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to classify posterior cervical screw systems into class II (special controls) and to continue to require a premarket notification (510(k)) to provide a reasonable assurance of safety and effectiveness of the device. A posterior cervical screw system is a device used to provide immobilization and stabilization in the cervical spine as an adjunct to spinal fusion surgery. The term ''posterior cervical screw systems'' is used to distinguish these devices from currently classified thoracolumbosacral pedicle screw systems for use in other spinal regions.

DATES: This rule is effective May 1, 2019.

ADDRESSES: For access to the docket to read background documents or comments received, go to *http://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.

FOR FURTHER INFORMATION CONTACT: Genevieve McRae, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1457, Silver Spring, MD 20993–0002, 301–796–6423, *genevieve.mcrae@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

Through this final rule, FDA is classifying posterior cervical screw systems (product code NKG) into class II (special controls). This decision was based upon the recommendation of the Orthopaedic and Rehabilitation Devices Panel (the Panel) and our 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.

B. Summary of the Major Provisions of the Final Rule

This final rule revises the identification language for posterior cervical screw systems, classifies posterior cervical screw systems into class II (special controls), and establishes the following special controls for posterior cervical screw systems with which manufacturers must comply: (1) The design characteristics of the device ensure that the geometry and material composition are consistent with the intended use of the device; (2) nonclinical performance testing must demonstrate mechanical function and durability of the implant; (3) device components must be demonstrated to be biocompatible; (4) validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components and device-specific instruments; and (5) device labeling must include a clear description of the technological features of the device, the intended use and indications for use, and certain specified device-specific warnings, precautions, and contraindications.

C. Legal Authority

FDA is issuing this rule under the authority of the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that apply to medical devices (21 U.S.C. 301 *et seq.*), including section 513(a) regarding device classes (21 U.S.C. 360c(a)), section 513(b) and (c) regarding device classification panels, and section 513(d) regarding device classification.

D. Costs and Benefits

We estimate that the final rule will affect 32 manufacturers of 38 products. Manufacturers of these affected products will incur one-time costs of $78.69 each to read and understand the rule, and will incur one-time labeling costs of $13,189 for each product. The present value of the total costs is estimated at $503,700. The annualized cost of this rule over 10 years is estimated to be $62,777 at a 7 percent discount rate and $52,853 at a 3 percent discount rate. We did not estimate quantifiable benefits of the final rule.

II. Background

A. History of This Rulemaking

In the **Federal Register** of March 10, 2016 (81 FR 12607), FDA issued a proposed rule to classify posterior cervical screw systems as class II with special controls, and proposed special controls for these devices, and invited interested persons to comment on the proposed regulation by June 8, 2016. These recommendations were based upon feedback received from the Panel on September 21, 2012.

B. Summary of Comments to the Proposed Rule

FDA received four sets of comments on the proposed rule from trade organizations, professional societies, and an individual. The comments within the scope of FDA's proposal to classify posterior cervical screw systems into class II (special controls) were supportive and included a few suggested clarifications and/or changes to the language of the proposed rule. We considered all comments in the development of this final rule and accepted several suggested changes, as discussed in section IV below.

III. Legal Authority

The FD&C Act (21 U.S.C. 301 *et seq.*), as amended, established a comprehensive system for the regulation of medical devices intended for human use. The FD&C Act establishes three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness (section 513(a) of the FD&C Act). The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under the general controls sections of the FD&C Act (sections 501, 502, 510, 516, 518, 519, or 520) (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j), or any combination of such sections) are sufficient to provide a reasonable assurance of the safety and effectiveness of the device; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device 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 the safety and effectiveness, and 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 as 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 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).

FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), as ''preamendments devices.'' Pursuant to section 513(d)(1) of the FD&C Act, FDA classifies these devices after FDA: (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 and has followed these procedures to classify posterior cervical screw systems.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

FDA received four sets of comments on the proposed rule by the close of the comment period. One of the comments received was regarding a different device type that is not associated with posterior cervical screw systems and is thus outside the scope of the rule. We describe and respond to the applicable comments in section IV.B and C. We have grouped certain comments under the same number because the subject matter of the comments is similar; conversely, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments, with separate numbers. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or

importance or the order in which it was received.

B. Description of General Comments and FDA Response

All comments within the scope of the rulemaking support FDA's proposed classification of posterior cervical screw systems into class II (special controls). One commenter notes that it supports the proposed classification of the device because ''the use of posterior cervical screw systems has been the standard of care for surgical management of cervical spine disorders arising from tumor, trauma, degerative [sic] disease and deformity for approximately 20 years.'' FDA agrees that the device type is well understood, which enables the establishment of special controls that provide a reasonable assurance of safety and effectiveness for these devices.

C. Specific Comments and FDA Response

(Comment 1) A commenter suggests removing the phrase ''utilizing pedicle and lateral mass screws'' when identifying and referring to posterior cervical screw systems as there are additional screw types that fall within these systems.

(Response 1) FDA agrees with this comment and has revised each relevant instance of this language within the regulation accordingly (*i.e.,* the recommended Precaution statement in § 888.3075(b)(5)(iii)(A) (21 CFR 888.3075(b)(5)(iii)(A)).

(Comment 2) A commenter recommends revising the proposed identification of ''posterior cervical screw systems'' to remove the specification of spinal levels for specific screw types listed in the identification and replacing it with a range of spinal levels applicable to all screw types utilized in the device.

(Response 2) FDA disagrees with the proposed edits to the identification language. Evidence in the scientific literature is not adequate to support the use of pars screws, translaminar screws, and transarticular screws outside of the specified level (C2) based upon anatomic differences between C2 and other levels. Therefore, this change is not accepted.

(Comment 3) A commenter notes that, while the preamble to the proposed rule specified that posterior cervical screw systems do not include dynamic features, the examples of dynamic features listed in the proposed identification language included ''non-uniform'' elements, which could be interpreted to include dual-diameter rods that may be a component of current posterior cervical screw systems. A dual-diameter rod is a rigid rod that transitions between two different diameters along its length.

(Response 3) FDA agrees that dual-diameter rods are often part of rigid posterior cervical screw systems and that the proposed identification language should be revised to clarify that dual diameter rods or plate/rod combinations are examples of ''longitudinal members,'' which may be included in posterior cervical screw systems. We have also revised the identification to specify that posterior cervical screw systems are rigidly fixed devices that do not contain dynamic features, including but not limited to, non-uniform longitudinal elements or features that allow more motion or flexibility compared to rigid systems.

(Comment 4) A commenter notes inconsistencies or errors in the indications for use in the proposed rule.

(Response 4) FDA agrees with this comment and has revised the indications for use within § 888.3075 to correct the noted errors. FDA has also clarified the language specifying the indications for use by replacing ''degenerative disease'' with ''degeneration'' to more appropriately reference the state to be treated and replacing ''radiographic studies'' with ''imaging studies (radiographs, computed tomography, magnetic resonance imaging)'' to account for the various imaging modalities that may be used in preoperative planning prior to implantation of a posterior cervical screw system.

(Comment 5) A commenter suggests that ''wear'' be removed from the list of potential means by which a device could fail.

(Response 5) FDA disagrees with this comment. Posterior cervical screw systems are comprised of multiple interconnecting components that have the potential to generate wear during spinal motion. Therefore, the definition of device failure has not been modified.

(Comment 6) A commenter recommends removing ''design characteristics'' as a special control because this item should be a requirement of all premarket notifications.

(Response 6) FDA disagrees with this comment. FDA considers the ''design characteristics'' special control necessary to help differentiate technological features for rigid posterior cervical screw systems, included within the scope of this regulation, from features considered to be dynamic.

(Comment 7) A commenter recommends revising the biocompatibility special control to be ''compliance with biocompatibility standards'' rather than ''[d]evice components must be demonstrated to be biocompatible'' because the majority of posterior cervical screw systems are made of materials that have a long history of safe use and, as such, are compatible with standards. Testing for compliance with biocompatibility standards would be relevant only for alternative or new materials.

(Response 7) FDA disagrees with this comment. The FD&C Act and FDA's regulations allow for flexibility in the methods for addressing certain regulatory requirements. Specifically, the substantial equivalence section of the FD&C Act (section 513(i)(1)(D)) states whenever the Secretary of Health and Human Services (the Secretary) requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such a request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly. Hence, there may be alternatives to FDA-recognized consensus standards to satisfy the special control related to the biocompatibility of devices within this device type.

(Comment 8) A commenter suggests modifying the first precaution within the labeling special control (§ 888.3075(b)(5)(iii)(a)) to include ''nerve roots'' as an anatomical structure to consider during preoperative planning.

(Response 8) FDA agrees with this comment. This precaution has been revised to include a reference to ''neurologic structures.''

(Comment 9) A commenter suggests that, within the Economic Analysis section of the proposed rule, it is unclear whether or not 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 9) FDA disagrees with this comment. As in the proposed rule, the language in the Economic Analysis of the final rule (see Ref. 1) states, ''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,'' which includes the

addition of the specified precaution statement.

(Comment 10) A commenter recommends minor editorial revisions to the risks and descriptive text associated with risks as outlined in the proposed rule.

(Response 10) FDA disagrees with this comment. The recommended edits were minor and would not substantively change the meaning of the risks and associated mitigations for the device; therefore, we do not accept these suggested edits in this final rule.

V. Effective Date

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

VI. Economic Analysis of Impacts

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 16 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 have decided not to certify the final rule and 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.

This final rule classifies posterior cervical screw systems as class II devices with special controls. Although these devices are currently unclassified, manufacturers are subject to premarket requirements similar to class II devices, with manufacturers receiving clearance to market 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).

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 (years)	
Benefits:							
Annualized Monetized $millions/year.	.....	.....	.....	2016	7	10	
				2016	3	10	
Annualized Quantified	.....	.....	.....	2016	7	10	
				2016	3	10	
Qualitative							
Costs:							
Annualized Monetized $millions/year.	0.063	.....	.....	2016	7	10	
	0.053			2016	3	10	
Annualized Quantified	.....	.....	.....	2016	7	10	
				2016	3	10	
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year.	.....	.....	.....	2016	7	10	
				2016	3	10	
	From:			To:			
Other Annualized Monetized $millions/year.	.....	.....	.....	2016	7	10	
				2016	3	10	
	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—E.O. 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		

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/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VII. 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.

VIII. Paperwork Reduction Act of 1995

This final rule establishes special controls that refer to currently approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 807 have been approved under OMB control number 0910–0625. The precaution labeling provisions in § 888.3075(b)(5) are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA. Rather, the following labeling in § 888.3075(b)(5)(iii)(A) and (b)(5)(iii)(B) is a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

IX. 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 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.

X. 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 address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. The full analysis of economic impacts is available in Docket No. FDA–2015–N–3785 for this final rule 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, 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, 360*l,* 371.

■ 2. Add § 888.3075 to subpart D to read as follows:

§ 888.3075 Posterior cervical screw system.

(a) *Identification.* Posterior cervical screw systems are comprised of multiple, interconnecting components, made from a variety of materials that allow an implant system to be built from the occiput to the upper thoracic spine to fit the patient's anatomical and physiological requirements, as determined by preoperative cross-sectional imaging. Such a spinal assembly consists of a combination of bone anchors via screws (*i.e.,* occipital screws, cervical lateral mass screws, cervical pedicle screws, C2 pars screws, C2 translaminar screws, C2 transarticular screws), longitudinal members (*e.g.,* plates, rods, including dual diameter rods, plate/rod combinations), transverse or cross connectors, interconnection mechanisms (*e.g.,* rod-to-rod connectors, offset connectors), and closure mechanisms (*e.g.,* set screws, nuts). Posterior cervical screw systems are rigidly fixed devices that do not contain dynamic features, including but not limited to: non-uniform longitudinal elements or features that allow more motion or flexibility compared to rigid systems.

Posterior cervical screw systems are intended to provide immobilization and stabilization of spinal segments in patients as an adjunct to fusion for acute and chronic instabilities of the cervical spine and/or craniocervical junction and/or cervicothoracic junction such as: (1) Traumatic spinal fractures and/or traumatic dislocations; (2) deformities; (3) instabilities; (4) failed previous fusions (*e.g.,* pseudarthrosis); (5) tumors; (6) inflammatory disorders; (7) spinal degeneration, including neck and/or arm pain of discogenic origin as confirmed by imaging studies (radiographs, CT, MRI); (8) degeneration of the facets with instability; and (9) reconstruction following decompression to treat radiculopathy and/or myelopathy. These systems are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

(b) *Classification.* Class II (special controls). The special controls for posterior cervical screw systems are:

(1) The design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.

(2) Nonclinical performance testing must demonstrate the mechanical function and durability of the implant.

(3) Device components must be demonstrated to be biocompatible.

(4) Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components and device-specific instruments.

(5) Labeling must include the following:

(i) A clear description of the technological features of the device including identification of device materials and the principles of device operation;

(ii) Intended use and indications for use including levels of fixation;

(iii) Device specific warnings, precautions, and contraindications that include the following statements:

(A) ''Precaution: Preoperative planning prior to implantation of posterior cervical screw systems should include review of cross-sectional imaging studies (*e.g.,* CT and/or MRI) to evaluate the patient's cervical anatomy including the transverse foramen, neurologic structures, and the course of the vertebral arteries. If any findings would compromise the placement of these screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.''

(B) ''Precaution: Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.''

(iv) Identification of magnetic resonance (MR) compatibility status;

(v) Cleaning and sterilization instructions for devices and instruments that are provided non-sterile to the end user, and;

(vi) Detailed instructions of each surgical step, including device removal.

Dated: March 22, 2019.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2019–06024 Filed 3–29–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Parts 478 and 479

[Docket No. ATF 2014R–42; AG Order No. 4419–2019]

Removal of Expired Regulations Concerning Commerce in Firearms and Ammunition and Machine Guns, Destructive Devices, and Certain Other Firearms

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule makes technical amendments to the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) regulations in the Code of Federal Regulations (CFR). These technical changes are being made to remove expired, obsolete, or unnecessary regulations; correct specific headings; and to reflect changes to nomenclature resulting from the transfer of ATF to the Department of Justice from the Department of the Treasury pursuant to the Homeland Security Act of 2002. The changes are designed to update and provide clarity throughout these regulations.

DATES: This rule is effective April 1, 2019.

FOR FURTHER INFORMATION CONTACT: Shermaine Kenner, Office of Regulatory Affairs, Enforcement Programs and Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice, 99 New York Avenue NE, Washington, DC 20226; telephone: (202) 648–7070 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

ATF administers regulations published in 27 CFR part 478, concerning commerce in firearms and ammunition, and part 479, concerning machine guns, destructive devices, and certain other firearms. ATF identified several technical amendments that are needed to provide clarity and accuracy to these regulations.

The technical changes made in this rule include the removal of expired regulations and regulations that are no longer applicable; the correction of section headings for accuracy; and a change in nomenclature resulting from the transfer of ATF to the Department of Justice from the Department of the Treasury pursuant to the Homeland Security Act of 2002.

Several sections are being removed or amended because the statute that formed the basis of those regulations is no longer in effect. The Public Safety and Recreational Firearms Act (the Act), enacted as part of the Violent Crime Control and Law Enforcement Act of 1994, Public Law 103–322, Title XI (1994), established a 10-year prohibition on the manufacture, transfer, or possession of ''semiautomatic assault weapons,'' as defined in the Act, as well as large capacity feeding devices. The Act expired on September 13, 2004, and ATF is removing or amending the following regulatory provisions that had, in whole or in part, implemented that Act and are therefore no longer effective:

Sections 478.40, 478.40a, 478.119, 478.132, and 478.153 are being removed and reserved as they are no longer effective.

Section 478.57 is being amended to remove paragraphs (b) and (c) as they are no longer effective.

Section 478.92 is being amended to remove the section heading and replace it with a heading that does not contain ''large capacity ammunition feeding devices'', and to remove paragraphs (a)(3) and (c), as they are no longer effective.

Section 478.116 is being amended to remove all references to ''ammunition feeding device'' as those references are no longer effective.

Section 478.171 is being amended to remove the last sentence referencing exportation of semiautomatic assault weapons as it is no longer effective.

The final rule makes two additional technical changes. First, § 478.95 is being amended to reflect the correct section number as a result of the transfer of ATF to the Department of Justice from the Department of Treasury pursuant to the Homeland Security Act of 2002. Second, § 479.32 is being amended to remove paragraphs (a) and (c) referencing special occupational tax rates prior to January 1988, as the information is obsolete.

II. Statutory Orders and Executive Review

A. Executive Orders 12866, 13563, and 13771

This rule has been drafted and reviewed in accordance with Executive Orders 12866, ''Regulatory Planning and Review,'' section 1(b), The Principles of Regulation; Executive Order 13563, ''Improving Regulation and Regulatory Review,'' section 1(b), General Principles of Regulation; and Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs.''