providing an incentive for entities to remit their assessments in a timely manner, with the intent of creating a fair and equitable process among all assessed entities.

Additionally, as previously mentioned, the Order provides for an exemption for entities that produce or import less than 20,000 pounds of processed raspberries annually. About 140 producers of raspberries for processing and 80 importers of processed raspberries pay assessments under the Order.

Regarding alternatives, one option to the proposed action would be to maintain the status quo and not prescribe late payment and interest charges for past due assessments. However, the Council determined that implementing such charges would help facilitate program administration by encouraging entities to pay their assessments in a timely manner. The Council reviewed rates of late payment and interest charges prescribed in other research and promotion programs and concluded that a 10 percent late payment charge and interest at a rate of 1 percent per month on the outstanding balance would be appropriate.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection and recordkeeping requirements that are imposed by the Order have been approved under OMB control number 0581–0093. This proposed rule would not result in a change to the information collection and recordkeeping requirements previously approved and would impose no additional reporting and recordkeeping burden on domestic producers, first handlers, and importers of processed raspberries.

As with all Federal promotion programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. Finally, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Regarding outreach efforts, the Council met on January 15, 2014, and unanimously made its recommendation. All of the Council's meetings, including meetings held via teleconference, are open to the public and interested persons are invited to participate and express their views.

We have performed this initial RFA regarding the impact of this proposed action on small entities and we invite comments concerning potential effects of this action on small businesses.

While this proposed rule set forth below has not received the approval of USDA, it has been determined that it is consistent with and would effectuate the purposes of the 1996 Act.

A 30-day comment period is provided to allow interested persons to respond to this proposal. Thirty-days is deemed appropriate because the Council would like to implement this incentive as soon as possible to facilitate the collection of assessments on a timely basis. All written comments received in response to this proposed rule by the date specified will be considered prior to finalizing this action.

List of Subjects in 7 CFR Part 1208

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Raspberry promotion, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1208 is proposed to be amended as follows:

PART 1208—PROCESSED RASPBERRY PROMOTION, RESEARCH, AND INFORMATION ORDER

■ 1. The authority citation for 7 CFR part 1208 continues to read as follows:

Authority: 7 U.S.C. 7411–7425; 7 U.S.C. 7401.

■ 2. Section 1208.3 is revised to read as follows:

§ 1208.3 Crop year.

Crop year means the 12-month period from October 1 through September 30 or such other period approved by the Secretary.

■ 3. Section 1208.7 is revised to read as follows:

§ 1208.7 Fiscal period.

Fiscal period means the 12-month period from October 1 through September 30 or such other period as approved by the Secretary.

■ 4. Section 1208.78 is revised to read as follows:

§ 1208.78 OMB control numbers.

The control numbers assigned to the information collection requirements by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, are OMB control number 0505–0001, and OMB control number 0581–0093.

■ 5. Section 1208.108 is revised to read as follows:

§ 1208.108 OMB control number.

The control number assigned to the information collection requirement in this subpart by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, is OMB control number 0581–0093.

■ 6. Subpart C—Rules and Regulations is added to read as follows:

Subpart C—Rules and Regulations

§ 1208.520 Late payment and interest charges for past due assessments.

(1) A late payment charge shall be imposed on any handler or importer who fails to make timely remittance to the Council of the total assessments for which such handler or importer is liable. The late payment will be imposed on any assessments not received within 30 calendar days of the date they are due. This one-time late payment charge shall be 10 percent of the assessments due before interest charges have accrued.

(2) In addition to the late payment charge, 1 percent per month interest on the outstanding balance, including any late payment and accrued interest, will be added to any accounts for which payment has not been received by the Council within 30 calendar days after the date the assessments are due. Such interest will continue to accrue monthly until the outstanding balance is paid to the Council.

Dated: November 5, 2014.

Rex A. Barnes,

Associate Administrator.

[FR Doc. 2014–26677 Filed 11–10–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2014–N–1205]

Orthopedic Devices; Reclassification of Thoracolumbosacral Rigid Pedicle Screw Systems; Classification and Effective Date of Requirement for Premarket Approval for Dynamic Stabilization Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is proposing in this administrative order to reclassify rigid pedicle screw systems, a

preamendments class III device, into class II (special controls); require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the dynamic stabilization systems, currently a subtype of pedicle screws, regardless of the indication for use; and clarify the device identification of pedicle screw spinal systems, to more clearly delineate between rigid pedicle screw systems and dynamic stabilization systems. FDA is proposing this action based on new information pertaining to the device type. This proposed action implements certain statutory requirements.

DATES: Submit either electronic or written comments on this proposed order by February 10, 2015. FDA intends that, if a final order based on this proposed order is issued, anyone who wishes to continue to market dynamic stabilization systems for the specified intended uses listed in section IX will need to file a PMA or a notice of completion of a PDP within 90 days of the effective date of the final order. See section XVII for the proposed effective date of any final order based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2014–N–1205, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (For paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2014–N–1205 for this order. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: 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 document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sergio M. de del Castillo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993, 301–796–6419, *sergio.dedelcastillo@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act of 2004 (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), 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 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, 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.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

A preamendments device that has been classified into class III and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such a preamendments device or to a device within that type may be marketed by means of premarket notification procedures (510(k) process) 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.

Although, under the FD&C Act, the manufacturer of a class III preamendments device may respond to the call for PMAs by filing a PMA or a notice of completion of a PDP, in practice, the option of filing a notice of completion of a PDP has not been used. For simplicity, although corresponding requirements for PDPs remain 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 the filing and receiving approval of a PMA.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended the device reclassification procedures under section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order. Section 608(b) of FDASIA amended section 515(b) of the FD&C Act, changing the process for requiring premarket approval for a preamendments class III device from rulemaking to an administrative order.

A. Reclassification

Pedicle screw spinal systems comprise multiple different device types:

Pedicle screw spinal systems (*i.e.,* rigid pedicle screw systems) when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease (DDD) and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment) are class III preamendment devices.

Dynamic stabilization systems (DSSs), when intended to provide

immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of DDD and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), are also class III preamendment devices.

DSSs, when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of any of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: Severe spondylolisthesis (grades 3 and 4) at L5–S1; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis), are class II devices.

FDA is proposing the reclassification of pedicle screw systems (i.e., rigid pedicle screw systems) when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of DDD and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment) from class III to class II.

When intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of DDD and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), the Agency proposes maintaining DSSs in class III. The Agency also proposes that DSSs be reclassified from class II to class III when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of any of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: Severe spondylolisthesis (grades 3 and 4) at L5–S1; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). As a result, FDA is proposing that all currently marketed DSSs be class III and now require a submission of a PMA.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see *Bell* v. *Goddard,* supra 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in ''medical science'' (*Upjohn,* 422 F.2d at 951). Whether data before the Agency are old or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, e.g., *General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Mfrs. Assoc.* v. *FDA,* 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985).)

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).)

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order reclassifying a 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 affected stakeholders, including patients, payors, and providers. In addition, the proposed order must set forth the proposed reclassification, and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including the public health benefits of the use of the device, and the nature and incidence (if known) of the risk of the device. (See section 513(e)(1)(A)(i) of the FD&C Act.)

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has considered rigid pedicle screw systems and decided that the device requires premarket notification (510(k) of the FD&C Act). Therefore, the Agency does not intend to exempt this proposed class II device from premarket notification (510(k)) submission as provided under section 510(m) of the FD&C Act.

B. Requirement for Premarket Approval Application

FDA is proposing to require PMAs for DSSs when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of any of the following indications for use: DDD; spondylolisthesis; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). 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 affected stakeholders, including patients, payors, and providers. FDA has held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to DSSs, and therefore, has met this requirement under section 515(b)(1) of the FD&C Act. As explained further in section X, a meeting of the device classification panel described in section 513(b) of the FD&C Act took place in 2013 (Ref. 1) to discuss whether DSSs should be reclassified or remain in class III. The panel recommended that DSSs should be classified as class III when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an

adjunct to fusion in the treatment of any of the following indications for use: DDD; spondylolisthesis; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). Section 515(b)(2) of the FD&C Act provides that a proposed order to require premarket approval shall contain: (1) The proposed order, (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device, (3) an opportunity for the submission of comments on the proposed order and the proposed findings, and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed order, consideration of any comments received, and a meeting of a device classification panel described in section 513(b) of the FD&C Act, issue a final order to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the FD&C Act, unless the reason for termination is that the device is a banned device under section 516 of the FD&C Act (21 U.S.C. 360f).

A preamendments class III device may be commercially distributed without a PMA until 90 days after FDA issues a final order (a final rule issued under section 515(b) of the FD&C Act prior to the enactment of FDASIA is considered to be a final order for purposes of section 501(f) of the FD&C Act (21 U.S.C. 351(f))) requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the FD&C Act, whichever is later. For DSSs, the preamendments class III devices that are the subject of this proposal, the later of these two time periods is the 90-day period. Because these devices were classified in 1998, the 30-month period has expired (63 FR 40025, July 27, 1998). Therefore, if the proposal to require premarket approval for DSSs for the uses described above is finalized, section 501(f)(2)(B) of the FD&C Act requires that a PMA for such device be filed within 90 days of the date of issuance of the final order. If a PMA is not filed for such device within 90 days after the issuance of a final order, the device would be deemed adulterated under section 501(f) of the FD&C Act.

DSSs are currently cleared in either one of two classifications—class II or class III—depending on the indications for use. Therefore, two separate actions are proposed in this proposed order. For those DSSs that are currently class II, the Agency is proposing to reclassify these devices to class III and to require submission of a PMA. For those DSSs that are preamendments class III, the Agency is proposing to maintain these devices in class III and to require submission of a PMA. As stated in the preceding paragraph, for those DSSs that are preamendments class III devices, if the proposal to require premarket approval for DSSs is finalized, section 501(f)(2)(B) of the FD&C Act requires that a PMA for such a device be filed within 90 days of the date of issuance of the final order. However, for reasons discussed below, FDA does not intend to ensure compliance with the 90-day deadline for PMA submission, for those DSSs that are currently in class III (for further discussion see sections IX and XII). Also, a preamendments device subject to the order process under section 515(b) of the FD&C Act is not required to have an approved investigational device exemption (IDE) (see part 812 (21 CFR part 812)) contemporaneous with its interstate distribution until the date identified by FDA in the final order requiring the filing of a PMA for the device. At that time, an IDE is required only if a PMA has not been filed. If the manufacturer, importer, or other sponsor of the device submits an IDE application and FDA approves it, the device may be distributed for investigational use. If a PMA is not filed by the later of the two dates, and the device is not distributed for investigational use under an IDE, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the FD&C Act, and subject to seizure and condemnation under section 304 of the FD&C Act (21 U.S.C. 334) if its distribution continues. Other enforcement actions include, but are not limited to, the following: shipment of devices in interstate commerce may be subject to injunction under section 302 of the FD&C Act (21 U.S.C. 332), and the individuals responsible for such shipment may be subject to prosecution under section 303 of the FD&C Act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for the class III devices that are the subject of this proposed order, if finalized.

In accordance with section 515(b)(2) of the FD&C Act, interested persons are being offered the opportunity to request reclassification of DSS for the uses described previously.

II. Regulatory History of the Device

In 1998, FDA issued a final rule classifying pedicle screw spinal systems as class II devices, when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, tumor, and failed previous fusion (63 FR 40025). For all other indications for use, pedicle screw spinal systems were deemed class III, for which a PMA is required. Classification of these devices followed the recommendations of the August 20, 1993, and July 22, 1994, meetings of the Orthopedic and Rehabilitation Devices Panel (the Panel). The Panel considered the reclassification of pedicle screw spinal systems for all indications, and recommended that FDA reclassify only certain indications into class II, leaving the other indications, including those of the devices that are the subject of this order, as class III devices (60 FR 51946, October 4, 1995).

In 2001, a technical amendment was published in the **Federal Register** to correct several errors and omissions in the July 27, 1998, final rule (66 FR 28051, May 22, 2001).

- The Agency identified the omission of one indication for use within the list of class III uses for pedicle screw spinal systems—the treatment of severe spondylolisthesis (grades 3 and 4) at the L5–S1 level as an adjunct to fusion. This indication was found to fall under preamendments status because devices were marketed for this indication prior to 1976.
- DDD and spondylolisthesis other than severe spondylolisthesis (grades 3 and 4) at L5–S1 were erroneously identified as postamendment uses, when in fact these are preamendment uses. While this error did not affect the final classification of the device for these uses (i.e., class III), it did affect the type of premarket submission required. Because these are preamendment uses, a PMA is not required until the Agency issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring submission of PMAs. Until that time, the devices may enter the

market after clearance of a premarket notification (510(k)) submission.

• DDD and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment) were the only class III uses specifically discussed by the panel during the August 20, 1993, and July 22, 1994, panel meetings. Therefore, the classification regulation was amended to state that pedicle screw spinal systems are deemed class III only for these specific uses.

In 2009, FDA published an order under section 515(i) of the FD&C Act (21 U.S.C. 360i) to call for information on the remaining class III 510(k) preadmendment device, including pedicle screw spinal systems when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of DDD and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment) (74 FR 16214, April 9, 2009). In response to that order, FDA received information from several device manufacturers who all recommended that pedicle screw spinal systems described in the preceding sentence should be reclassified to class II. The manufacturers stated that safety and effectiveness of these devices may be assured via special controls, including labeling, biocompatibility, sterility, and mechanical testing.

A meeting of the Orthopedic and Rehabilitation Devices Panel was convened on May 22, 2013 (2013 Panel). The 2013 Panel recommended that rigid pedicle screw systems should be classified as class II when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of DDD and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment). The special controls discussed by the 2013 Panel included those proposed by device manufacturers in response to the 2009 order; as well as an additional control proposed in this order of design characteristics. The 2013 Panel also recommended that DSSs, a subset of pedicle screw spinal systems, be classified as class III when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion, regardless of the indications for use, requiring submission of a PMA. FDA is not aware of new information that would provide a basis for a different recommendation or finding.

III. Device Description

Pedicle screw spinal systems (i.e., rigid pedicle screw systems) are multiple component devices made from a variety of materials that allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly may consist of a combination of hooks, screws, longitudinal members (e.g., plates, rods, plate/rod combinations), transverse or cross connectors, and interconnection mechanisms (e.g., rod-to-rod connectors, offset connectors). Rigid pedicle screw systems provide immediate rigid fixation to the spinal column as an adjunct to spinal fusion procedures.

Since the 1998 final classification, changes in technological characteristics have occurred, leading to the emergence of a new type of pedicle screw spinal system, known as DSSs. DSSs are a subset of the pedicle screw spinal systems regulated under § 888.3070 (21 CFR 888.3070). DSSs are defined as systems that contain one or more non-uniform and/or non-metallic longitudinal elements (e.g., polymer cords, moveable screw heads, springs) that allow more motion or flexibility (e.g., bending, rotation, translation) compared to rigid systems and do not provide immediate rigid fixation to the spinal column as an adjunct to spinal fusion procedures.

FDA is proposing to modify the identification language from the way it is presently written in § 888.3070(a) to include this technology and is also seeking comments on alternative means of providing further distinction between rigid pedicle screw systems and DSSs.

IV. Proposed Reclassification

FDA is proposing that rigid pedicle screw systems subject to this order be reclassified from class III to class II. In this proposed order, the Agency has identified special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls (including prescription use), would provide reasonable assurance of their safety and effectiveness. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and § 860.130, based on new information with respect to the devices and taking into account the public health benefit of the use of the device and the nature and known incidence of the risk of the device, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of DDD and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment). FDA believes that this new information is sufficient to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in the next section, and that these special controls, together with the general controls, will provide a reasonable assurance of safety and effectiveness for rigid pedicle screw systems intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment.

Section 510(m) of the FD&C Act authorizes the Agency to exempt class II devices from premarket notification (510(k)) submission. FDA has considered rigid pedicle screw systems and decided that the device requires premarket notification (510(k) of the FD&C Act). Therefore, the Agency does not intend to exempt this proposed class II device from premarket notification (510(k)) submission as provided under section 510(m) of the FD&C Act.

The Agency is also taking this opportunity to revise the identification for pedicle screw spinal systems to distinguish between rigid pedicle screw systems currently in class II and DSSs currently in class III. The proposal calling for a PMA requirement for DSS is discussed in section X.

In addition, the Agency is taking the opportunity to add the following indications for use to § 888.3070—spinal stenosis and lordosis (a subset of spinal curvatures and deformities). Spinal stenosis and lordosis are conditions that can be treated with fusion surgery, which can include the use of rigid pedicle screw systems, and the Agency believes that the inclusion of spinal stenosis and lordosis in the regulation is appropriate. It is believed

that the risks to health listed in this document encompass the risks associated with treating patients with both spinal stenosis and lordosis using rigid pedicle screw systems as part of the procedure. It is expected that the special controls identified are appropriate to provide reasonable assurance of the safety and effectiveness for rigid pedicle screw systems when used as an adjunct to fusion to treat spinal stenosis and lordosis. In addition, since the 1998 final classification, the Agency has found pedicle screw spinal systems for the indications of spinal stenosis and lordosis substantially equivalent to devices previously cleared under § 888.3070.

V. Risks to Health

After considering available information, including the recommendations of the advisory committee (panels) for the classification of these devices, FDA has evaluated the risks to health associated with the use of pedicle screw spinal systems (i.e., rigid pedicle screw systems), when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of DDD and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment). FDA determined that the following risks to health are associated with its use:

- Device failure—Components may deform, fracture, wear, loosen, or disassemble, resulting in a mechanical or functional failure; this may result in back/leg pain, neurological deficit/injury, or loss of correction.
- Failure at the bone/implant interface—Components may loosen, migrate, or disengage from the bone; this may result in back/leg pain, neurological deficit/injury, or loss of correction.
- Tissue injury—Intraoperative and post-operative risks of tissue injury include: Bone fracture, injury to blood vessels or viscera, neurologic injury, dural tear or cerebrospinal fluid leak and skin penetration or irritation, post-operative wound problems including infection, and hematoma/seroma.
- Adverse tissue reactions—Device material(s) may elicit adverse tissue reactions, such as foreign body response, metal allergy, and metal toxicity.
- Device malposition—Risks of device malposition may include difficulty or inability to implant the device components or incorrect placement of the device.
- Pseudarthrosis—The risk of nonunion, or pseudarthrosis, signifies failure of bony fusion and potential instability or pain.

The risks to health presented to the 2013 Panel such as cardiac, respiratory, gastrointestinal, and death are considered general surgical risks associated with the surgical procedure to implant rigid pedicle screw systems (Ref. 1); these risks are not directly associated with rigid pedicle screw systems and therefore are not included in the above list of risks. Failure of the rigid pedicle screw system as a result of the risks to health listed previously may result in the need for reoperation, revision, or removal.

While presented to the 2013 Panel as a potential risk, graft settling would not be considered a device-specific risk. Rather, it represents a potential mechanism for the development of pseudarthrosis, instability, or lack of correction. Further, graft settling is expected in patients undergoing fusion surgery and does not necessarily result in adverse clinical sequelae. Thus, this item does not appear in the above list.

The 2013 Panel stated that the risks to health for DSSs appear similar to those identified for rigid pedicle screw systems; however, as discussed in section X, few data exist to confirm the risk profile for these devices. Therefore, the risks to health cannot be fully characterized for this device type. FDA is also seeking comments on further characterizing the risks to health for DSSs.

VI. Summary of Reasons for Reclassification

If properly manufactured and used, FDA believes that pedicle screw spinal systems (i.e., rigid pedicle screw systems), when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), should be reclassified into class II because special controls, in addition to general controls, can be established to provide reasonable assurance of the safety and effectiveness of the device, and because general controls themselves are insufficient to provide reasonable assurance of its safety and effectiveness. In addition, there is now adequate effectiveness information sufficient to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Reclassification Is Based

FDA believes that the identified special controls, in addition to general controls, are necessary to provide reasonable assurance of safety and effectiveness of rigid pedicle screw systems. Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and § 860.130, based on new information with respect to the device and taking into account the public health benefit of the use of the device and the nature and known incidence of the risk of the device, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II. The Agency has identified special controls that would provide reasonable assurance of their safety and effectiveness. Rigid pedicle screw systems are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device.

Since the 1998 final classification, when FDA classified pedicle screw spinal systems into class III, sufficient evidence has been developed to support a reclassification of rigid pedicle screw systems to class II with special controls, when such devices are intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment). FDA has been reviewing these devices for many years and their risks are well known. The risks to health are identified in section V, and FDA believes these risks can be adequately mitigated by special controls.

FDA's presentation to the 2013 Panel included a summary of the available safety and effectiveness information for rigid pedicle screw systems for treatment of the previously described uses, including comprehensive reviews of the available literature and adverse event reports from the Manufacturer and User Facility Device Experience (MAUDE) database. Based on the available safety and effectiveness information that supports that rigid pedicle screw systems may be beneficial for patients undergoing fusion treatment of the previously described conditions, FDA recommended that rigid pedicle screw systems be reclassified to class II (special controls) when such devices are intended to provide immobilization and stabilization of spinal segments in the

thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment). The 2013 Panel discussed and made recommendations regarding the regulatory classification of rigid pedicle screw systems to either reconfirm to class III (subject to premarket approval application) or reclassify to class II (subject to special controls) as directed by section 515(i) of the FD&C Act. The 2013 Panel agreed with FDA's conclusion that the available scientific evidence is adequate to support the safety and effectiveness of rigid pedicle screw systems for these uses.

The 2013 Panel also agreed with the identified risks to health outlined in section V. The 2013 Panel also recommended that allergic reaction to the device and its materials should be included as a risk to health. FDA agrees with the 2013 Panel's recommendation and has included this risk. The 2013 Panel agreed with FDA's proposed special controls outlined in section VIII.

The 2013 Panel transcript and other meeting materials are available on FDA's Web site (Ref. 1).

VIII. Proposed Special Controls

FDA believes that the following special controls, in addition to general controls (including applicable prescription-use restrictions and continuing 510(k) notification requirements), are sufficient to mitigate the risks to health described in section V for rigid pedicle screw systems:

- The design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.
- Non-clinical performance testing must demonstrate the mechanical function and durability of the implant.
- Device components must be demonstrated to be biocompatible.
- Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components and device-specific instruments.
- Labeling must specifically include the following:
  - A clear description of the technological features of the device including identification of device materials and the principles of device operation;
  - intended use and indications for use including levels of fixation;
  - identification of magnetic resonance compatibility status;
  - cleaning and sterilization instructions for devices and instruments that are provided non-sterile to the end user; and
  - detailed instructions of each surgical step, including device removal.

Table 1 summarizes how FDA believes the risks to health identified in section V can be mitigated by the proposed special controls.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR RIGID PEDICLE SCREW SYSTEMS

Identified risks to health	Mitigation method
Device Failure	Design characteristics. Non-clinical performance testing. Labeling.
Failure of Bone Implant Interface	Design characteristics. Biocompatibility. Non-clinical performance testing. Labeling.
Tissue Injury	Labeling.
Adverse Tissue Reaction	Design characteristics. Biocompatibility. Sterility. Labeling.
Device Malposition	Labeling.
Pseudoarthrosis	Non-clinical performance testing. Biocompatibility. Labeling.

In addition, under 21 CFR 801.109, the sale, distribution and use of rigid pedicle screw systems are restricted to prescription use. Prescription-use restrictions are a type of general control under section 513(a)(1)(A)(i) of the FD&C Act. Under § 807.81, the device would continue to be subject to 510(k) notification requirements.

While the 2013 Panel recommended that training be a special control, we believe that the general control of prescription use is an adequate substitute. Furthermore, these devices are for prescription use only, which makes adequate surgeon training implicit.

IX. Dates New Requirements Apply

In accordance with section 515(b) of the FD&C Act, FDA is proposing to require that a PMA be filed with the Agency for DSSs that are preamendments class III devices within 90 days after issuance of any final order based on this proposal. In addition, in accordance with section 513(e) of the FD&C Act, FDA is proposing to require that a PMA be filed with the Agency for DSSs that will be reclassified from class II to class III. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found to be substantially equivalent to such a device, will be permitted to continue marketing such class III device during FDA's review of the PMA, provided that the PMA is timely filed. FDA intends to review any PMA for the device within 180 days of the date of filing. FDA cautions that under section 515(d)(1)(B)(i) of the FD&C Act, the Agency may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the Agency finds that ''the continued availability of the device is necessary for the public health.''

Under the FD&C Act, preamendments class III DSSs currently in distribution for which no PMA is submitted within 90 days of a final order calling for DSS, or for which a denial is rendered on its filed PMA, will be considered adulterated under section 501(f)(1) of the FD&C Act. Nonetheless, for reasons discussed below, FDA does not intend to ensure compliance with the 90-day

deadline for PMA submissions, for those manufacturers of currently marketed class III preamendment DSSs (see further discussion in section XII). Instead, FDA is proposing to consider allowing continued distribution for manufacturers of currently marketed DSSs who notify FDA of their intent to file a PMA within 90 days from the issuance of the final order based on this proposal. The notification of the intent to file a PMA submission should include a list of all part numbers for which a manufacturer plans to seek marketing approval through its PMA. FDA proposes further to allow continued distribution for DSS devices lawfully distributed for 30 months from the issuance of a final order requiring the filing of a PMA for such devices. Manufacturers should be able to collect additional scientific evidence, to the extent any is necessary, and prepare PMA submissions, in this time. No new devices will be allowed into interstate commerce without approval of a PMA. We request comment on whether it is appropriate to allow continued distribution and, if so, whether the 30 month period proposed is reasonable.

FDA intends that under § 812.2(d), the publication in the **Federal Register** of any final order based on this proposal will include a statement that, as of the date on which a PMA is required to be filed, the exemptions from the requirements of the IDE regulations for preamendments class III devices in § 812.2(c)(1) and (c)(2) will cease to apply to any device that is: (1) Not legally on the market on or before that date or (2) legally on the market on or before that date but for which a PMA is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA for a class III device is not filed with FDA within 90 days after the date of issuance of any final order requiring premarket approval for the device, the device would be deemed adulterated under section 501(f) of the FD&C Act. The device may be distributed for investigational use only if the requirements of the IDE regulations are met. The requirements for significant risk devices include submitting an IDE application to FDA for review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued under § 812.30. FDA usually recommends that IDE applications be submitted to FDA at least 30 days before the end of the 90-day period after the issuance of the final order to avoid interrupting any ongoing investigations.

However, FDA does not intend to enforce compliance with IDE and PMA requirements for manufacturers of DSSs who notify FDA of their intent to file a PMA for such devices within 90 days and file a PMA within 30 months after the date of issuance of any final order requiring premarket approval for these devices. As stated previously in Section I.B, because DSSs are currently cleared in either one of two classifications—class II or class III—if the proposal to require a PMA is finalized, two different requirements would exist for submission of a PMA for the same device type (90 days and 30 months, respectively). Similarly, if the proposal to require a PMA is finalized, two different requirements would exist for an approved IDE to be in effect. The Agency believes that all DSS manufacturers should be provided the same amount of time to comply with the IDE requirements. Therefore, to avoid an imbalance in IDE requirements for the same device type, we propose that an approved IDE need not be in effect until 30 months after the date of issuance of any final order requiring premarket approval for DSSs. FDA recommends that manufacturers file a pre-submission to discuss data requirements that may be necessary to support their individual PMA submission.

Unlike DSSs, rigid pedicle screw systems, when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of DDD and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment) can currently be marketed after receiving clearance of a 510(k) submission. Because FDA is proposing to reclassify these devices as class II requiring clearance of a 510(k) submission, this order, if finalized, will not impose any new requirements on rigid pedicle screw systems when intended for these uses.

X. Device Subject to the Proposal to Require a PMA—DSSs (Proposed § 888.3070(a)(2))

A. Identification

DSSs are a subset of the pedicle screw spinal systems regulated under § 888.3070. These systems are defined as systems that contain one or more of the following features (including but not limited to): Non-uniform or non-metallic longitudinal elements, features that allow more motion or flexibility compared to rigid systems, or features that do not provide the system immediate rigid fixation. DSSs encompass a large variety of designs and may perform differently as compared to rigid pedicle screw systems.

B. Summary of Data

As described and summarized in section X.C, FDA concludes that there is very limited valid scientific evidence available for DSSs when used as an adjunct to fusion in the treatment of any spinal condition. Because of the limited data available, FDA believes that safety and effectiveness have not been established, the risks to health cannot be fully characterized, special controls cannot be developed, and the benefits of DSSs cannot be evaluated. The 2013 Panel agreed that the risks appeared similar to those identified for rigid pedicle screw systems; however, few data exist to confirm this. The 2013 Panel recommended that DSSs should remain in class III (subject to premarket approval application) because insufficient information currently exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls would provide such assurance.

C. Risks to Health

As required by section 515(b) of the FD&C Act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that DSSs have an approved PMA and (2) the benefits to the public from the use of DSSs.

These findings are based on the reports and recommendations of the 2013 Panel for the classification of these devices and any additional information that FDA has obtained.

Very limited data currently exist regarding the safety and effectiveness of DSSs when used as an adjunct to fusion in the treatment of any of the following indications for use: DDD; spondylolisthesis; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). FDA's presentation to the 2013 Panel included a summary of the available safety and effectiveness information for DSSs for treatment of the above described uses, including identification of the limited literature and adverse event reports from the MAUDE database (Ref. 1). The limited information from the available published literature, as well as confounding factors (e.g., lack of identification of the indications for use, data from devices that are not legally marketed in the United States), did not

permit any meaningful conclusions to be drawn. The MAUDE search described in section 7.4 of FDA's presentation to the 2013 Panel suggests a potentially higher rate of incidence of serious adverse events (e.g., device breakage, pain, and reoperation) compared to rigid pedicle screw systems; however, the overall number of adverse event reports are very low, due to the limited use and distribution of these devices. (Ref. 1, FDA Executive Summary, pages 31–33). Given the lack of data available for these devices, FDA believes that the safety and effectiveness profile for DSSs is not well established, the risks to health are not fully characterized for this device subtype, and special controls cannot be developed at this time to mitigate the risks to health. The 2013 Panel agreed that the DSSs risks appeared similar to those listed for rigid pedicle screw systems; however, few data exist to confirm the risk profile for these devices. The 2013 Panel recommended that DSSs should remain in class III (subject to premarket approval application) because insufficient information currently exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls would provide such assurance.

Because the benefits of DSSs for the above described uses are unknown, it is not currently possible to truly estimate the direct effect of the DSSs on patient outcomes. However, claims for the devices state the devices have the potential to benefit the public in the following ways: Reduced risk for screw fracture and reduced stress-shielding at the treated level.

XI. PMA Requirements

A PMA for a DSS, when used as an adjunct to fusion in the treatment of any spinal condition, must include the information required by section 515(c)(1) of the FD&C Act. Such a PMA should also include a detailed discussion of the risks to health, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought. A PMA must include valid scientific evidence to demonstrate reasonable assurance of the safety and effectiveness of the device for its intended use (see § 860.7(c)(1)). Valid scientific evidence is ''evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use . . . Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness.'' (See § 860.7(c)(2).)

XII. Implementation Strategy for Currently Marketed DSSs

For clarification, if this proposed order is finalized, and under section 501(f)(2)(B), PMAs for currently marketed DSSs are required to be filed on or before 90 days after the date of issuance of a final order in the **Federal Register**. However, for currently marketed DSSs, FDA does not intend to ensure compliance with this 90-day deadline until 30 months after that deadline (i.e., 33 months after the issuance of the final order) for class III preamendments DSSs, as long as notice of intent to file a PMA is submitted within 90 days of issuance of the final order. The notification of the intent to file a PMA submission must include a list of all part numbers for which a manufacturer plans to seek marketing approval through its PMA. Manufacturers should be able to collect additional scientific evidence, to the extent any is necessary, and prepare PMA submissions, in this time. No new devices will be allowed into interstate commerce without approval of a PMA.

In conducting any clinical studies, DSSs may be distributed for investigational use if the requirements of the IDE regulations (part 812) are met. There will be neither extended period for filing an IDE nor exemption from IDE requirements, and studies may not be initiated without appropriate IDE approvals, where necessary.

XIII. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA for a device, FDA is required by section 515(b)(2)(D) of the FD&C Act to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to the classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the FD&C Act.

A request for a change in the classification of DSSs, when used as an adjunct to fusion in the treatment of any spinal condition, is to be in the form of a reclassification petition containing the information required by § 860.123, including new information relevant to the classification of the device.

XIV. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices and section 515(b) of the FD&C Act provided for FDA to issue regulations to require approval of an application for PMA for preamendments devices or devices found to be substantially equivalent to preamendments devices. Because sections 513(e) and 515(b) of the FD&C Act, as amended by FDASIA, require FDA to issue final orders rather than regulations, FDA will continue to codify reclassifications and requirements for approval of a PMA, resulting from changes issued in final orders, in the CFR.

Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this proposed order, we are proposing to revoke the requirements in § 888.3070 related to the classification of rigid pedicle screw systems when used for immobilization and stabilization as an adjunct to fusion in the treatment of DDD and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment) as class III devices and to codify the reclassification of rigid pedicle screw systems when used for immobilization and stabilization as an adjunct to fusion in the treatment of DDD and spondylolisthesis (other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment) into class II.

XV. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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.

XVI. Paperwork Reduction Act of 1995

This proposed order refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231. The collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120.

The effect of this order, if finalized, is to shift DSSs devices from the 510(k) premarket notification process to the PMA process. To account for this change, FDA intends to transfer some of the burden from OMB control number 0910–0120, which is the control number for the 510(k) premarket notification process, to OMB control number 0910–0231, which is the control number for the PMA process. FDA estimates that it will receive 16 new PMAs for DSS as a result of this order, if finalized. Based on FDA's most recent estimates, this will result in 16,601 hours burden increase to OMB control number 0910–0231. FDA also estimates that there will be 16 fewer 510(k) submissions as a result of this order, if finalized. Based on FDA's most recent estimates, this will result in 2,179 hours decrease to OMB control number 0910–0120. Therefore, on net, FDA expects a burden hour increase of 14,422 hours due to this proposed regulatory change.

The collections of information in part 812 have been approved under OMB control number 0910–0078.

XVII. Proposed Effective Date

FDA is proposing that any final order based on this proposal become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final order.

XVIII. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

XIX. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. FDA, the May 22, 2013 Panel transcript and other meeting materials (*http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm352525.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, it is proposed that 21 CFR part 888 be amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 888.3070 is amended by revising paragraphs (a) and (b)(2), adding paragraph (b)(3), and revising paragrpah (c) to read as follows:

§ 888.3070 Pedicle screw spinal system.

(a) *Identification.* (1) Rigid pedicle screw systems are prescription devices comprised of multiple components, made from a variety of materials that allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of hooks, screws, longitudinal members (e.g., plates, rods, plate/rod combinations), transverse or cross connectors, and interconnection mechanisms (e.g., rod-to-rod connectors, offset connectors). These systems are intended for immediate rigid fixation as an adjunct to fusion.

(2) Dynamic stabilization systems are defined as systems that contain one or more non-uniform and/or non-metallic longitudinal elements (e.g., polymer cords, moveable screw heads, springs) that allow more motion or flexibility (e.g., bending, rotation, translation) compared to rigid pedicle screw systems and do not provide immediate rigid fixation to the spinal column as an adjunct fusion.

(b) * * *

(2) Class II (special controls), when a rigid pedicle screw system is intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment. These pedicle screw spinal systems must comply with the following special controls:

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

(ii) Non-clinical performance testing must demonstrate the mechanical function and durability of the implant.

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

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

(v) Labeling must bear all information required for the safe and effective use of the device, specifically including the following:

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

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

(C) Identification of magnetic resonance compatibility status;

(D) Cleaning and sterilization instructions for devices and instruments that are provided nonsterile to the end user; and

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

(3) Class III (premarket approval) when a dynamic stabilization system is intended to provide stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion for any indication.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [*DATE 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE* ***FEDERAL REGISTER***] for any dynamic stabilization system that was in commercial distribution before May 28, 1976, or that has, on or before [*DATE 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE* ***FEDERAL REGISTER***] been found to be substantially equivalent to a pedicle

screw spinal system that was in commercial distribution before May 28, 1976. Any other dynamic stabilization system shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: November 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26726 Filed 11–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 924

[SATS No. MS–024–FOR; Docket No. OSMRE–2014–0005; S1D1SS S08011000 SX066A00067F144S180110; S2D2SS S08011000SX066A00033F14XS501520]

Mississippi Abandoned Mine Land Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Mississippi Abandoned Mine Land Reclamation (AMLR) Plan (hereinafter, the Mississippi Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Mississippi has requested concurrence from the Secretary of the Department of the Interior with its certification of completion of all coal-related reclamation objectives. If the Secretary concurs with the certification, Mississippi intends to request AMLR funds to pursue projects in accordance with section 411 of SMCRA.

This document gives the times and locations that the Mississippi Plan and this proposed amendment to that plan are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., c.d.t., December 12, 2014. If requested, we will hold a public hearing on the amendment on December 8, 2014. We will accept requests to speak at a hearing until 4:00 p.m., c.d.t. on November 28, 2014.

ADDRESSES: You may submit comments, identified by SATS No. MS–024–FOR, by any of the following methods:

- Mail/Hand Delivery: Sherry Wilson, Director, Birmingham Field Office, Office of Surface Mining Reclamation and Enforcement, 135 Gemini Circle, Suite 215, Homewood, Alabama 35209; Telephone: (205) 290–7282.
- Fax: (205) 290–7280.
- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Mississippi Plan, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address of our Birmingham Field Office listed above during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Birmingham Field Office or going to *www.regulations.gov.*

Sherry Wilson, Director, Birmingham Field Office, Office of Surface Mining Reclamation and Enforcement, 135 Gemini Circle, Suite 215, Homewood, Alabama 35209, Telephone: (205) 290–7282, Email: *swilson@osmre.gov.*

In addition, you may review a copy of the amendment during regular business hours at the following location:

Mississippi Office of Geology, Department of Environmental Quality, 700 N. State Street Jackson, Mississippi 39202, Telephone: (601) 961–5519.

FOR FURTHER INFORMATION CONTACT: Sherry Wilson, Director, Birmingham Field Office. Telephone: (205) 290–7282. Email: *swilson@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Mississippi Plan
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Mississippi Plan

The Abandoned Mine Land Reclamation Program was established by Title IV of the Act, (30 U.S.C. 1201 *et seq.*) in response to concerns over extensive environmental damage caused by past coal mining activities. The program is funded by a reclamation fee collected on each ton of coal that is produced. The money collected is used to finance the reclamation of abandoned coal mines and for other authorized activities. Section 405 of the Act allows States and Indian tribes to assume exclusive responsibility for reclamation activity within the State or on Indian lands if they develop and submit to the Secretary of the Interior for approval, a program (often referred to as a plan) for the reclamation of abandoned coal mines. On September 27, 2007, the Secretary of the Interior approved the Mississippi plan. You can find background information on the Mississippi Plan, including the Secretary's findings, the disposition of comments, and the approval of the plan in the September 27, 2007, **Federal Register** (72 FR 54832). No amendments have previously been made to the Mississippi Plan.

II. Description of the Proposed Mississippi Amendment

By letter dated August 11, 2014 (Administrative Record No. MS–0424), Mississippi indicated to OSMRE that it has instituted the necessary processes to reclaim the remaining coal related problems within the State. As such, Mississippi seeks certification of completion of all coal-related problems. If this request is approved by OSMRE, it will mark the addressing, for the present, of all known existing coal-related problems within the State that are eligible for funding under Mississippi's AMLR Program.

If approved, the certificate of completion will be codified at 30 CFR 924.25. In accordance with 30 CFR 875.13(c), Mississippi may then implement a program under Section 411 of SMCRA.

OSMRE is seeking public comment on the adequacy of Mississippi's certification that it has addressed all reclamation relating to abandoned coal mine lands. In addition, OSMRE is aware of the potential for problems to occur in the future related to pre-August 3, 1977, coal mining. In accordance with 30 CFR 875.13(a)(3), Mississippi agrees to acknowledge and give top priority to any coal-related problem(s) that may be found or occur after submission of the certificate of completion.

The full text of the plan amendment is available for you to read at the locations listed above under **ADDRESSES** or at *www.regulations.gov.*

III. Public Comment Procedures

Under the provisions of 30 CFR 884.15(a), we are seeking your comments on whether Mississippi's proposed amendment satisfies the applicable reclamation plan approval criteria of 30 CFR 884.14. If we approve