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Issued in Kansas City, Missouri, on February 10, 2016.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA-2011-N-0661]

Effective Date of Requirement for Premarket Approval for Total Metal-on-Metal Semi-Constrained Hip Joint Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

DATES: This order is effective on February 18, 2016.

FOR FURTHER INFORMATION CONTACT: Sergio M. de del Castillo, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993, 301-796-6419.

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 (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), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) 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 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 (both the preamendments and substantially equivalent devices are referred to as preamendments class III devices) may be marketed without submission of a PMA until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval. Section 515(b)(1) of the FD&C Act directs FDA to issue an order requiring premarket approval for a preamendments class III device.

Although, under the FD&C Act, the manufacturer of a preamendments class

III 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 rarely been used. For simplicity, although the PDP option remains available to manufacturers in response to a final order under section 515(b) of the FD&C Act, this document will refer only to the requirement for the filing of, and obtaining approval of, a PMA.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended 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.

FDA is requiring PMAs for total metal-on-metal (MoM) semi-constrained hip joint systems (heretofore referenced as "MoM hips"), which include the following two specific preamendments class III devices: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

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 published a proposed order to require PMAs for MoM hips in the **Federal Register** of January 18, 2013 (78 FR 4094), and convened a meeting of a device classification panel for MoM hips as discussed in the proposed order and in this document.

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.

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 MoM hips, the later of these two time periods is the 90-day period. Therefore, section 501(f)(2)(B) of the FD&C Act requires that a PMA for such devices be filed within 90 days of the date of issuance of this final order. If a PMA is not filed for such devices within 90 days after the issuance of this final order, the devices will be deemed adulterated under section 501(f) of the FD&C Act.

Also, a preamendment 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).

FDA held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to MoM hips on August 8, 2001, and therefore, has met this requirement under section 515(b)(1) of the FD&C Act. The panel recommended that the devices remain in class III because there was insufficient information to establish special controls; the panel also agreed unanimously that MoM hips are for a use which is of substantial importance in preventing impairment of human health (Ref. 1). FDA is not aware of new information that would provide a basis for a different recommendation or

findings, and the recent reports and evaluations discussed in the proposed order further support that reclassification of MoM hips is not appropriate. Furthermore, the problems identified in the medical device reporting systems and recalls for MoM hips further indicate the need to review these devices under a PMA to provide reasonable assurance of their safety and effectiveness.

FDA received and has considered several sets of comments from nine commenters on the proposed order, as discussed in section II.

II. Public Comments in Response to the Proposed Order

In response to the January 18, 2013 (78 FR 4094), proposed order to require premarket approval for MoM hips, FDA received several sets of comments from nine commenters. These comments, as well as the Agency's consideration of them, are summarized further in this section.

Six commenters generally agreed with FDA's proposal to require PMAs for MoM hips. One commenter (the American Academy of Orthopaedic Surgeons, also referred to as AAOS) stated that the existing data is not adequate to support reclassification of MoM hips because special controls could not be established to provide a reasonable assurance of device safety and effectiveness. This comment echoes the findings and recommendations of the August 8, 2001, panel.

Another commenter stated that MoM hip resurfacing devices should be classified as Class III; however, MoM hip resurfacing devices are not regulated under 21 CFR 888.3320 or 21 CFR 888.3330 and are not the subject of this order.

Several commenters requested that all currently marketed MoM hips be removed from the market, either through a FDA-initiated recall or voluntary action by the device manufacturer.

As explained in more detail in section III of this order, if a PMA for a currently marketed MoM hip is not filed on or before the 90th day past the effective date of this order, that device will be deemed adulterated under section 501(f)(1)(A) of the FD&C Act, and commercial distribution of the device must cease immediately. FDA intends to take appropriate action to ensure compliance with the 90-day deadline for the submission of PMAs. The Agency believes this information adequately addresses the commenters' concern.

One commenter recommended standardizing the modularity and other design features of MoM hips to mitigate

adverse events attributed to the manufacturing process for these devices. The Agency does not believe sufficient information exists to establish any manufacturing standards or specific technical specifications for MoM hips that could potentially be generalized for this technology to mitigate adverse events.

One commenter requested that the Agency set revision surgery standards. Revision surgery involves a complex clinical decision that falls within the practice of medicine, which FDA generally does not regulate. In addition, insufficient information exists to establish any standards for revision surgery. FDA notes, however, that the American Association of Hip and Knee Surgeons, the American Academy of Orthopaedic Surgeons, and the Hip Society issued a consensus statement regarding assessment of risks in patients implanted with MoM hips, including factors to consider for revision surgery, based on currently available information (Ref. 2). FDA's Web site for MoM hips also provides some general considerations regarding revision surgery (Ref. 3).

One commenter requested that MoM hips not be used in women, including those of child-bearing age, and children who are still growing (*i.e.*, skeletally immature). As noted in the proposed order and as presented during the June 27–28, 2012, panel meeting, labeling for MoM hips includes warnings or contraindications for skeletally immature patients and patients who are pregnant or who may become pregnant (Ref. 4). In addition, the Agency will review all data included in the required PMA for a MoM hip to determine what information needs to be included in the device labeling to assure its safe and effective use, including any warnings and contraindications. The removal of any current contraindications for these patient populations would need to be supported by valid scientific evidence, in accordance with 21 CFR 860.7.

One commenter requested the adoption of standards for metal ion levels in the serum of patients implanted with a MoM hip. As discussed in detail during the June 28, 2012, panel meeting, there are challenges to implementing metal ion testing into clinical evaluations of patients treated with MoM hips, as well as challenges in the interpretation of metal ion testing results (Ref. 5). For example, the equipment and expertise required to conduct such testing are currently not widely available in health care facilities. In addition, there can be significant variability in test results, based on a number of factors, including

the laboratory conducting the testing (inter-laboratory variability) and the specific MoM hip implanted in the patient. Further, insufficient information exists to establish a definitive correlation between metal ion levels and clinical outcomes. Therefore, the Agency does not believe such standards can be adequately developed at this time. Nonetheless, the Agency acknowledges the importance of using metal ion levels within the overall clinical assessment of patients implanted with MoM hips. On May 6, 2011, under section 522 of the FD&C Act (21 U.S.C. 360l), FDA ordered manufacturers of MoM hips to conduct postmarket surveillance studies of these devices. As part of these studies, manufacturers are required to study the effects of metal ion concentrations in the bloodstream. The Agency will use the data from these studies to determine if any additional recommendations can be developed with respect to metal ion levels.

One commenter stated that FDA should affirmatively assert that common law liability claims relating to MoM hips that are included under this final order, which were cleared through the 510(k) process before the effective date of this final order, should not be preempted under section 521 of the FD&C Act (21 U.S.C. 360k). Section 521 of the FD&C Act includes an express preemption provision that preempts certain state requirements that are “different from, or in addition to” certain Federal requirements applicable to devices. Two Supreme Court cases: *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), address the scope of this provision. In *Lohr*, the Court held that design defect, manufacturing, and failure to warn claims relating to a 510(k)-cleared device were not preempted because there were no Federal “requirements” imposed by the 510(k) review where (1) the device could “take any particular form for any particular reason,” and (2) the general Federal manufacturing and labeling requirements were not specific to the device in question. *Id.* at 493, 497–502. In contrast, the Court determined in *Riegel* that the PMA review imposed Federal “requirements” under section 521 of the FD&C Act because FDA required that the PMA-approved device be made with almost no deviations from the specifications in the approved PMA. 552 U.S. at 323. The *Riegel* Court went on to hold that the Riegels’ common law claims were preempted where New York law imposed requirements on the PMA-approved device that were

“different from, or in addition to” the Federal requirements. *Id.* at 327–330. As seen in these cases, the preemption analysis under section 521 of the FD&C Act depends on whether “requirements” imposed by State law are different from or in addition to “requirements” imposed by Federal law. This determination involves resolution of a number of critical factual issues, including identifying the applicable State and Federal (if any) requirements that relate to the claims asserted, defining the scope of those requirements, and evaluating their relationship to one another. Although *Lohr* may be relevant to the situation described in the comment, FDA notes that the inquiry into preemption needs to consider the context and all relevant facts. The situation described in the comment is fairly generalized, and as such, FDA believes it would not be helpful to opine on this issue at this point in time.

Finally, several comments recommended actions that address broader issues or programmatic areas, such as changes to the postmarket surveillance process for all class III medical devices, recommendations for research studies, and the establishment of a “trust fund” for healthcare reimbursement of failed MoM hips. These requests are outside the scope of the regulatory actions described in this order.

III. The Final Order

Under section 515(b)(3) of the FD&C Act, FDA is adopting its findings as published in the proposed order (78 FR 4094), and is issuing this final order to require the filing of a PMA for MoM hips, which specifically includes the following two device types: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis. This final order will revise 21 CFR part 888.

Under the final order, a PMA is required to be filed on or before May 18, 2016, for any of these preamendments class III devices that were in commercial distribution before May 28, 1976, or that has been found by FDA to be substantially equivalent to such a device on or before May 18, 2016. An applicant of a device subject to this order that was legally in commercial distribution before May 28, 1976, or that has been found to be substantially equivalent to a device that was legally in commercial distribution before May 28, 1976, may continue marketing such class III device during FDA’s review of the PMA provided that the PMA is filed on or

before May 18, 2016. However, if FDA denies approval of the PMA, then the device will be deemed adulterated under section 501(f)(1)(A) of the FD&C Act, and commercial distribution of the device must cease immediately. Any other device subject to this order is required to have an approved PMA in effect before it may be marketed. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 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.”

If a PMA for any of the preamendments class III devices subject to this order is not filed on or before May 18, 2016, that device will be deemed adulterated under section 501(f)(1)(A) of the FD&C Act, and commercial distribution of the device must cease immediately. FDA requests that manufacturers take action to prevent the further use of MoM hips for which no PMA has been filed.

The device may, however, be distributed for investigational use, if the applicable requirements of the IDE regulations (part 812), including obtaining IDE approval, are met on or before 90 days after the effective date of this order. There will be no extended period for filing an IDE or exemption from the IDE requirements (see § 812.2(d)), and clinical studies may not be initiated without appropriate IDE approvals, as required.

IV. Analysis of Environmental Impact

The Agency has 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.

V. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in 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 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; 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 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

VI. Codification of Orders

Prior to the amendments by FDASIA, section 515(b) of the FD&C Act provided for FDA to issue regulations to require approval of an application for premarket approval for preamendments devices or devices found substantially equivalent to preamendments devices. Section 515(b) of the FD&C Act, as amended by FDASIA, provides for FDA to require approval of an application for premarket approval for such devices by issuing a final order following the issuance of a proposed order in the **Federal Register**. FDA will continue to codify the requirement for an application for premarket approval in the Code of Federal Regulations (CFR). Therefore, under section 515(b)(1) of the FD&C Act, as amended by FDASIA, in this final order, FDA is requiring approval of an application for premarket approval for total MoM semi-constrained hip joint systems, which include the following two specific preamendments class III devices: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis; and the Agency is making the language in 21 CFR 888.3320 and 888.3330 consistent with this final order.

VII. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA, Orthopaedic and Rehabilitation Devices Panel transcript, August 8, 2001. Available at <http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3780t1.rtf>.
2. Kwon *et al.* “Risk Stratification Algorithm for Management of Patients with Metal-on-Metal Hip Arthroplasty.” *Journal of Bone and Joint Surgery, American Volume*, 96:e4, 2014.
3. FDA, Metal-on-Metal Hip Implants Web site, Information for Orthopaedic Surgeons. Available at <http://www.fda.gov/MedicalDevices/>

ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241667.htm.

4. FDA, Orthopaedic and Rehabilitation Devices Panel, FDA Executive Summary, June 27–28, 2012. Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM309302.pdf>.
5. FDA, Orthopaedic and Rehabilitation Devices Panel transcript, June 28, 2012. Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM313605.pdf>.

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 21 CFR part 888 continues to read as follows:

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

- 2. Section 888.3320 is amended by revising paragraph (c) to read as follows:

§ 888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.

* * * * *

(c) *Date PMA or notice of completion of 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 May 18, 2016, for any hip joint metal/metal semi-constrained prosthesis with a cemented acetabular component that was in commercial distribution before May 28, 1976, or that has, on or before May 18, 2016, been found to be substantially equivalent to a hip joint metal/metal semi-constrained prosthesis with a cemented acetabular component that was in commercial distribution before May 28, 1976. Any other hip joint metal/metal semi-constrained prosthesis with a cemented acetabular component shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

- 3. Section 888.3330 is amended by revising paragraph (c) to read as follows:

§ 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

* * * * *

(c) *Date PMA or notice of completion of 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 May 18, 2016, for any hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component that was in commercial distribution before May 28, 1976, or that has, on or before May 18, 2016, been found to be substantially equivalent to a hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component that was in commercial distribution before May 28, 1976. Any other hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: February 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–03331 Filed 2–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9750]

RIN 1545–BM59

Reporting of Original Issue Discount on Tax-Exempt Obligations; Basis and Transfer Reporting by Securities Brokers for Debt Instruments and Options

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to information reporting by brokers for transactions involving debt instruments and options, including the reporting of original issue discount (OID) on tax-exempt obligations, the treatment of certain holder elections for reporting a taxpayer's adjusted basis in a debt instrument, and transfer reporting for section 1256 options and debt instruments. The regulations in this document provide guidance to brokers and payors and to their customers.

DATES:

Effective date: These regulations are effective on February 18, 2016.