

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Dassault Service Bulletin F20–789, also referred to as 789, dated December 9, 2014.

(ii) Dassault Service Bulletin F50–531, also referred to as 531, dated December 9, 2014.

(iii) Dassault Service Bulletin F200–133, also referred to as 133, dated December 9, 2014.

(3) For service information identified in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; Internet <http://www.dassaultfalcon.com>.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

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Thomas Groves,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2014–N–0297]

Obstetrical and Gynecological Devices; Reclassification of Surgical Instrumentation for Use With Urogynecologic Surgical Mesh

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reclassifying surgical instrumentation for use with urogynecologic surgical mesh from class I (general controls) exempt from premarket notification to class II (special controls) and subject to premarket notification, and identifying them as “specialized surgical instrumentation for use with

urogynecologic surgical mesh.” FDA is designating special controls that are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is reclassifying this device on its own initiative based on new information.

DATES: This order is effective January 6, 2017. See further discussion in section V, “Implementation Strategy.”

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SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended, established a comprehensive system for the regulation of medical devices intended for human use. 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).

Devices that were in commercial distribution before the enactment of the 1976 amendments on May 28, 1976, are generally referred to as preamendments devices. Under section 513(d) of the FD&C Act, 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, are generally referred to as postamendments devices. Postamendments devices are automatically classified into class III without any FDA rulemaking process (section 513(f) of the FD&C Act). Postamendments 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, under 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.

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the mechanism for reclassifying a device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act 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 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 Co. 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*, 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., *Gen. 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. 1985), cert. denied, 474 U.S. 1062 (1986).) 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 premarket approval application (PMA). (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).)

The process for issuing a final reclassification order is specified in section 513(e)(1) of the FD&C Act. 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 to a public docket.

In the **Federal Register** of May 1, 2014, FDA published a proposed order to reclassify surgical mesh for transvaginal pelvic organ prolapse (POP) repair from class II to class III (79 FR 24634). In the same order, FDA also proposed to reclassify specialized surgical instrumentation for use with urogynecologic surgical mesh (hereafter referred to as urogynecologic surgical mesh instrumentation) from class I—regulated under § 876.4730 (21 CFR 876.4730) (manual gastroenterology-urology surgical instrument and accessories) and § 878.4800 (21 CFR 878.4800) (manual surgical instrument for general use)—to class II and subject to premarket notification. In the **Federal Register** of January 5, 2016, FDA published two final orders that: (1) Reclassified surgical mesh for transvaginal POP repair from class II to class III (81 FR 354) and (2) required the filing of a PMA or notice of completion of a product development protocol for surgical mesh for transvaginal POP repair (81 FR 364).

In the May 1, 2014 proposed order, FDA stated that it would convene a panel specifically to discuss reclassification of urogynecologic surgical mesh instrumentation before finalizing reclassification of those devices. FDA held a meeting on February 26, 2016 (81 FR 938, January 8, 2016), of the Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee (“the Panel”), a device classification panel described in section 513(b) of the FD&C Act. Prior to the meeting, all panel members were provided a comprehensive Executive Summary regarding the reclassification of urogynecologic surgical mesh instrumentation, which included information contained in the May 1, 2014, proposed order, a summary of comments submitted to the public docket on the proposed reclassification of urogynecologic surgical mesh instrumentation, and information regarding FDA’s risk-based classification and regulation of medical devices (Ref. 1).

The Executive Summary also included a new FDA analysis of perioperative adverse events related to urogynecologic surgical mesh procedures. FDA conducted a new analysis to supplement the adverse event information discussed in the May 1, 2014, proposed order, which included adverse events related to POP procedures that were: (1) Reported in

clinical studies and systematic literature reviews in the published literature or (2) submitted to the Manufacturer and User Facility Device Experience (MAUDE) database between January 1, 2011, and December 31, 2013. FDA’s new analysis was a more comprehensive analysis of perioperative adverse events associated with stress urinary incontinence (SUI) procedures (retropubic, transobturator, mini-sling) and POP procedures (transvaginal repair and transabdominal repair (transabdominal POP repair is referred to as sacrocolpopexy)).

Adverse events related to a urogynecologic surgical mesh procedure, and that might be attributable to the specialized instrumentation used during the procedure, are typically submitted to FDA or described in published literature with reference to the surgical mesh and not the instrumentation. Therefore, it can be difficult to distinguish adverse events related to the urogynecologic surgical mesh instrumentation from those related to the surgical mesh. As noted in the proposed order, FDA believes it is reasonable to assume that perioperative adverse events—*i.e.*, those observed during the procedure or shortly thereafter (*e.g.*, organ perforation, hemorrhage and bleeding, nerve injury and pain)—are caused by or related to the use of specialized surgical instrumentation to insert, place, fix, or anchor the surgical mesh during the urogynecologic procedure. Hereafter, the term “perioperative adverse events” will be used in this document to refer to adverse events that FDA believes are caused by or related to the specialized instrumentation that is the subject of this reclassification.

In its new, more comprehensive analysis, FDA conducted a search of the relevant, scientific literature published between January 1, 1997, and December 8, 2015, to identify perioperative adverse events associated with urogynecologic surgical mesh procedures (see the 207 studies included as references in the Executive Summary provided to the Panel (Ref. 1)). The search criteria consisted of a combination of terms related to adverse events (type, timing with respect to surgery), type of urogynecologic condition, type of surgical instrumentation, study design, device name, and manufacturer name. FDA then filtered the results to identify those studies that describe perioperative adverse events during one of the following urogynecologic surgical mesh procedures: SUI-retropubic, SUI-transobturator, SUI-mini-sling, POP-transvaginal, and POP-sacrocolpopexy. All perioperative adverse events were

classified into one of the following categories: “organ perforation and injury,” “vascular injury and bleeding,” or “nerve injury and pain.” FDA then computed an adverse event rate for each study by dividing the number of patients that experienced one of these types of events by the total number of patients included in the study.

FDA also conducted a search of the Medical Device Reporting (MDR) database for relevant adverse events reported between January 1, 2008, and December 2, 2015. There are no FDA product codes specifically assigned to urogynecologic surgical mesh instrumentation; therefore, FDA first identified reports that were associated with a product code assigned to urogynecologic surgical mesh. FDA filtered the resulting injury and death reports to identify and analyze those that described perioperative adverse events. By stratifying its analysis by product code for the urogynecologic surgical mesh, which depends, in part, on the procedure type (*e.g.*, OTP is assigned to mesh used during POP-transvaginal procedures, OTN for mesh used during SUI-retropubic or transobturator procedures), FDA characterized the perioperative adverse events associated with the different kinds of urogynecologic surgical mesh instrumentation used during SUI and POP procedures.

After completing its review of the published literature and MDR database, and aggregating its findings, FDA determined that perioperative adverse events occur during all types of urogynecologic surgical mesh procedures to treat female SUI and POP. Moreover, and as discussed in the Executive Summary (Ref. 1, Attachments 6–8), FDA made the following findings from its review of the published literature:

- The rate of “vascular injury and bleeding” varied between 0.4–29.4 percent in studies describing retropubic SUI procedures; 0.2–11.9 percent in studies describing transobturator SUI procedures; 1–20.5 percent in studies describing mini-sling SUI procedures; 0.7–7.7 percent in studies describing transvaginal POP repair procedures; and 2.8 percent for one study describing sacrocolpopexy procedures;
- the rate of “organ perforation and injury” varied between 0.3–23.8 percent for retropubic SUI procedures; 0.2–5.8 percent for transobturator SUI procedures, 0.2–2.6 percent for mini-sling SUI procedures; 0.7–13.1 percent for transvaginal POP repair procedures; and 3.6 percent for one study describing sacrocolpopexy procedures; and

- the rate of “nerve injury and pain” varied between 0.1–5.3 percent for retropubic SUI procedures; 0.8–30.8 percent for transobturator SUI procedures, 1.1–4.1 percent for mini-sliding SUI procedures; 6.0–39.1 percent for transvaginal POP repair procedures; and 14.9 percent for one study describing sacrocolpopexy procedures.

FDA presented a summary of the information contained in the Executive Summary during the February 26, 2016, panel meeting (Ref. 2). The Panel then discussed whether urogynecologic surgical mesh instrumentation should be reclassified, and if so, whether it should be reclassified from class I (general controls) to class II (special controls) or class III (premarket approval) (Ref. 3). The Panel discussed a variety of potential causes for the perioperative adverse events identified by FDA (e.g., instrumentation design, surgeon error, and surgeon experience). The Panel consensus was that the risks to health of urogynecologic surgical mesh instrumentation that FDA identified in the proposed order and Executive Summary (*i.e.*, perioperative risks; damage to blood vessels, nerves, connective tissue, and other structures; adverse tissue reaction; and infection) was a complete and accurate list.

The Panel agreed with FDA that the device is not purported or represented for a use in supporting or sustaining human life, or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. In light of this assessment, the Panel consensus was that urogynecologic surgical mesh instrumentation did not meet the definition of a class III device. The Panel also agreed with FDA that general controls alone are not sufficient to provide reasonable assurance of safety and effectiveness for the device, and that there is sufficient information to establish special controls to provide such assurance. When considering the specific special controls proposed by FDA, two Panel members requested that an additional special control be the submission of clinical data. However, after additional discussion, the Panel unanimously agreed that the special controls proposed by FDA, which did not include the submission of clinical data, would appropriately mitigate the risks to health of this device. As such, the Panel recommended that urogynecologic surgical mesh instrumentation be reclassified from class I (general controls) exempt from premarket notification to class II (special controls).

II. Key Changes From Proposed Order

In the final order, FDA is modifying two of the special controls included in the proposed order. First, FDA is revising § 884.4910(b)(2) (21 CFR 884.4910(b)(2)) to require a demonstration that the device, if reusable, can be adequately reprocessed. Reprocessing validation will help to ensure that reusable urogynecologic surgical mesh instrumentation is fit for subsequent use after being previously used or contaminated. The validated processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization. Although FDA recognized in the proposed order that “the risk of infection due to inadequate sterilization and/or reprocessing instructions/procedures can be mitigated through sterilization validation testing and the inclusion of validated reprocessing instructions in the device labeling,” proposed § 884.4910(b)(2) addressed sterilization only. FDA believes this revised special control will help to mitigate the risks posed by infection from reusable urogynecologic surgical mesh instrumentation.

Second, FDA is revising § 884.4910(b)(4) to require that non-clinical performance testing demonstrate that the device: (1) Meets all design specifications and performance requirements and (2) performs as intended under anticipated conditions of use. In the proposed order, FDA specified that “[b]ench and/or cadaver testing must demonstrate safety and effectiveness in expected-use conditions.” FDA has revised the reference to “bench and/or cadaver testing” to “non-clinical performance testing” to allow for additional types of non-clinical testing that will also mitigate the corresponding risks to health. FDA is making other revisions to this provision as noted previously to provide further clarity.

III. Public Comments in Response to the Proposed Order

FDA received comments regarding the proposed reclassification of urogynecologic surgical mesh instrumentation from class I to class II. A summary of the comments and FDA’s responses are provided in this section. Certain comments are grouped together under a single number because the subject matter is similar. The number assigned to each one is purely for organizational purposes and does not signify the comment’s value, importance, or the order in which it was received.

(Comment 1) Several comments supported reclassification of urogynecologic surgical mesh instrumentation, with some comments supporting reclassification into class II and others supporting reclassification into class III.

(Response 1) FDA agrees with comments supporting reclassification of urogynecologic surgical mesh instrumentation into class II and disagrees with comments that support reclassification into class III. Based on information set forth in the proposed order (79 FR 24634), FDA tentatively concluded in that order that certain specified special controls, in addition to general controls, were necessary to mitigate the risks to health for urogynecologic surgical mesh instrumentation, and as such, proposed to reclassify the device from class I to class II (79 FR 24634 at 24640). FDA continues to believe that there is sufficient information to establish special controls to provide a reasonable assurance of safety and effectiveness for this device, and thus does not believe this device should be reclassified into class III.

FDA’s new, more comprehensive, adverse event analysis provides further support for the risks to health of this device that FDA identified in the proposed order (see section I; Ref. 1), and the special controls established by FDA are specifically intended to mitigate those risks. For example, FDA’s new MDR analysis revealed that failures of urogynecologic surgical mesh instrumentation (e.g., needle detachments, breaks, or bends; covering sheath breaks or tears) occur during both SUI and POP procedures, and these failures are associated with perioperative adverse events. The special control established at § 884.4910(b)(4) addresses these failures and the risk of perioperative injuries by requiring a demonstration that the device meets all design specifications and performance requirements.

Based on all of this information, the Panel consensus was that urogynecologic surgical mesh instrumentation meets the statutory definition of a class II device and does not meet the statutory definition of a class III device (see section I; Ref. 3).

Because FDA has determined that general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness for this device, and there is sufficient information to establish special controls to provide such an assurance, FDA is reclassifying the device into class II.

(Comment 2) One comment requested that urogynecologic surgical mesh

instrumentation have the same classification as the surgical mesh with which it is indicated to be used.

(Response 2) Surgical mesh indicated for urogynecologic procedures is a class III device when it is indicated for transvaginal POP repair (see 81 FR 354; § 884.5980) and a class II device when it is indicated for all other urogynecologic procedures, such as sacrocolpopexy and treatment of female SUI (see § 878.3300). FDA characterized the risk profile of different kinds of urogynecologic surgical mesh instrumentation by analyzing adverse events associated with the use of this specialized instrumentation and stratifying them by the type of urogynecologic procedure for which they were used. The results indicate that the risk profile of urogynecologic surgical mesh instrumentation used with class III surgical mesh during transvaginal POP repair is comparable to that of urogynecologic surgical mesh instrumentation used with class II surgical mesh during other kinds of urogynecologic procedures (see section I; Ref. 1). Urogynecologic surgical mesh instrumentation used in all types of urogynecologic surgical mesh procedures appears to have a similar risk-benefit profile, and therefore FDA believes these devices should have the same classification.

Moreover, as previously discussed, based on information included in the proposed order (79 FR 24634), FDA's comprehensive adverse event analysis (see Ref. 1), and the Panel's deliberations and determinations, FDA has determined that urogynecologic surgical mesh instrumentation is a class II device because general controls alone cannot provide a reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance. As such, FDA is reclassifying these devices from class I to class II.

(Comment 3) One comment stated that the scope of the urogynecologic surgical mesh instrumentation reclassification was unclear, and it could be interpreted that the reclassification applies only to instrumentation used for transvaginal POP repair rather than for instrumentation used for any urogynecologic surgical mesh procedure.

(Response 3) FDA disagrees that the scope of the instrumentation reclassification was unclear in the May 1, 2014, proposed order. FDA included the description in the identification of urogynecologic surgical mesh instrumentation in proposed § 884.4910(a) stating that surgical

instrumentation for use with surgical mesh for urogynecologic procedures is a prescription device used to aid in insertion, placement, fixation, or anchoring of surgical mesh for procedures including transvaginal POP repair, sacrocolpopexy (transabdominal POP repair), and treatment of female SUI. This description, which is not substantively changing in the final order, makes clear that all urogynecologic surgical mesh instrumentation—whether used for transvaginal POP repair or other urogynecologic surgical mesh procedures—falls under this reclassification.

(Comment 4) One comment stated that data provided in the proposed order to support the instrumentation reclassification was based only on POP procedures, that valid scientific evidence had not been provided to support the instrumentation reclassification, and that no evidence was provided to support the risks that were identified in the proposed order.

(Response 4) First, FDA acknowledges that the data provided to support the instrumentation reclassification in the May 1, 2014, proposed order derived only from surgical mesh procedures indicated for POP. FDA subsequently conducted a new, more comprehensive analysis of perioperative adverse events associated with a variety of SUI procedures (retropubic, transobturator, mini-sling) and POP procedures (transvaginal repair and sacrocolpopexy) by reviewing adverse events included in the relevant, scientific, published literature and adverse events submitted to the MDR database. Based on this analysis, FDA determined that perioperative adverse events occur during all types of SUI and POP procedures (see section I; Ref. 1). FDA also discovered that in the published literature, the highest reported rates of “organ perforation and injury,” “vascular injury and bleeding,” and “nerve injury and pain” were distributed across different types of urogynecologic surgical mesh procedures rather than only occurring during one specific type, such as transvaginal POP repair. FDA believes these results provide further support for the reclassification of these devices into class II, and also supports the scope of this reclassification, which encompasses specialized instrumentation used during all types of urogynecologic surgical mesh procedures. After presenting the proposed order and this new information to the Panel at the February 26, 2016, meeting, the Panel recommended that urogynecologic surgical mesh instrumentation be

reclassified from class I (general controls) exempt from premarket notification to class II (special controls) (Ref. 3). FDA agrees with the Panel's recommendations and is reclassifying these devices from class I to class II.

Second, FDA disagrees that valid scientific evidence was not provided in the May 1, 2014, proposed order to support reclassification of urogynecologic surgical mesh instrumentation. Valid scientific evidence is defined in § 860.7(c)(2) as evidence from well-controlled investigations, other types of studies and 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. (See also section 513 of the FD&C Act). In the proposed order, FDA reviewed perioperative adverse events included in published studies of surgical mesh used during POP procedures. These publications constitute “valid scientific evidence” because they are controlled studies (Refs. 7–10, 12, 14) and collections of well-documented case histories conducted by qualified experts (Refs. 4–6, 11, 13).

Finally, FDA disagrees that no evidence was provided to support the risks of urogynecologic surgical mesh instrumentation identified in the proposed order. In the proposed order, FDA specifically referenced clinical studies and systematic literature reviews in the published literature that included reports of perioperative adverse events (e.g., bleeding, hematoma, and blood loss; organ perforation; and neuromuscular problems) to support the proposed reclassification. Moreover, the risks of “perioperative injury” and “pelvic pain and neuromuscular problems” were also identified during FDA's search of the MAUDE database. As discussed in the proposed order, 843 reports in the MAUDE database analysis related to bleeding, hematoma, and blood loss; 42 reports related to organ perforation; and 196 reports of neuromuscular problems. FDA acknowledges that no data were provided to support the identified risks of “infection” and “adverse tissue reaction.” Although there are many possible causes for “infection” and “adverse tissue reaction” during a urogynecologic surgical mesh procedure, as FDA noted in the proposed order (see 79 FR 24634 at 24639), FDA believes “infection” and “adverse tissue reaction” are general risks that apply to all devices that

contact the patient and need to be used sterile.

As discussed throughout this document, FDA subsequently conducted a more comprehensive search of the relevant, scientific, published literature and MDR database to evaluate the risks of urogynecologic surgical mesh instrumentation. A summary of the findings from these reviews is in the Executive Summary (Ref. 1) and was provided in our presentation to the Panel on February 26, 2016 (Ref. 2). The findings from the literature review—which were confirmed by the MDR database review—provide further support for the risks identified and discussed in the proposed order.

Based on this information, the Panel consensus was that the four risks to health of urogynecologic surgical mesh instrumentation that FDA identified in the proposed order is a complete and accurate list (Ref. 3).

(Comment 5) One comment, which was submitted after the proposed order issued and before the Panel meeting was held, stated that the proposed order should be withdrawn until Panel input was obtained.

(Response 5) FDA disagrees. The process followed by FDA in reclassifying this device is in accordance with section 513(e)(1) of the FD&C Act. This provision requires, in relevant part, that issuance of a final administrative order reclassifying a device be preceded by a proposed order and a meeting of a device classification panel. There is no requirement that a proposed order be “withdrawn” after its issuance but before the Panel meeting, and the rationale for doing so is not clear to FDA.

IV. The Final Order

Under section 513(e) of the FD&C Act, FDA is adopting its findings as published in the proposed order for urogynecologic surgical mesh instrumentation, with the modifications discussed in section II of this document. For the reasons set forth in the proposed order and in this document, FDA concludes that general controls are insufficient to provide a reasonable assurance of safety and effectiveness for urogynecologic surgical mesh instrumentation, and there is sufficient information to establish special controls to provide such assurance.

FDA is issuing this final order to reclassify urogynecologic surgical mesh instrumentation from class I (general controls) exempt from premarket notification to class II (special controls) and subject to premarket notification, and identifying them as “specialized

surgical instrumentation for use with urogynecologic surgical mesh.” FDA is also establishing special controls, which are set forth in § 884.4910(b)(1) through (5).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of urogynecologic surgical mesh instrumentation, and therefore, this device is not exempt from premarket notification requirements.

V. Implementation Strategy

The order is effective January 6, 2017.

Manufacturers of urogynecologic surgical mesh instrumentation that have not been legally marketed prior to January 6, 2017, must obtain 510(k) clearance and demonstrate compliance with the special controls included in this final order before marketing the device.

Manufacturers of urogynecologic surgical mesh instrumentation that have been legally marketed prior to January 6, 2017, must obtain 510(k) clearance and demonstrate compliance with the special controls included in this final order by January 8, 2018, for those devices if they wish to continue offering them for sale.

VI. 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.

VII. 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 807, subpart E, have been approved under OMB control number 0910–0120 and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

VIII. 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. Although section 513(e) of the FD&C Act as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order, we are codifying the reclassification of specialized surgical instrumentation for use with urogynecologic surgical mesh into class II in § 884.4910.

IX. 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 <https://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. Executive Summary of the February 26, 2016, meeting of the Gastroenterology-Urology Devices Panel (available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM487224.pdf>).
2. FDA presentation to Panel members at the February 26, 2016, meeting of the Gastroenterology-Urology Devices Panel (available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM490205.pdf>).
3. Transcript of the February 26, 2016, meeting of the Gastroenterology-Urology Devices Panel (available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM491862.pdf>).
4. Caquant, F., et al., “Safety of Trans Vaginal Mesh Procedure: Retrospective Study

of 684 Patients,” *Journal of Obstetrics and Gynecology Research*, 34(4):449–456, 2008.

5. Maher, C.F., et al., “Surgical Management of Pelvic Organ Prolapse in Women,” *Cochrane Database of Systematic Review*, 4: CD004014, 2010.

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List of Subjects in 21 CFR Part 884

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 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 1. The authority citation for part 884 continues to read as follows:

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

■ 2. Add § 884.4910 to subpart E to read as follows:

§ 884.4910 Specialized surgical instrumentation for use with urogynecologic surgical mesh.

(a) *Identification.* Specialized surgical instrumentation for use with urogynecologic surgical mesh is a prescription device specifically intended for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures. These procedures include transvaginal pelvic organ prolapse repair, sacrocolpopexy (transabdominal pelvic organ prolapse repair), and treatment of female stress urinary incontinence. Examples of specialized surgical instrumentation include needle passers and trocars, needle guides, fixation tools, and tissue anchors. This device is not a manual gastroenterology-urology surgical instrument and accessories (§ 876.4730) or a manual surgical instrument for general use (§ 878.4800).

(b) *Classification.* Class II (special controls). The special controls for specialized surgical instrumentation for use with urogynecologic surgical mesh are:

(1) The device must be demonstrated to be biocompatible;

(2) The device must be demonstrated to be sterile and, if reusable, it must be demonstrated that the device can be adequately reprocessed;

(3) Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the requested shelf life;

(4) Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use; and

(5) Labeling must include:

(i) Information regarding the mesh design that may be used with the device;

(ii) Detailed summary of the clinical evaluations pertinent to use of the device;

(iii) Expiration date; and

(iv) Where components are intended to be sterilized by the user prior to initial use and/or are reusable, validated methods and instructions for sterilization and/or reprocessing of any reusable components.

Dated: December 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31862 Filed 1–5–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2016–0396; FRL–9957–80–Region 5]

Air Plan Approval; Ohio; Redesignation of the Cleveland, Ohio Area to Attainment of the 2008 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) finds that the Cleveland-Akron-Lorain, Ohio area (Cleveland area) is attaining the 2008 ozone National Ambient Air Quality Standard (NAAQS or standard) and is redesignating the area to attainment for the 2008 ozone NAAQS, because the area meets the statutory requirements for redesignation under the Clean Air Act (CAA). The Cleveland area includes Ashtabula, Cuyahoga, Geauga, Lake, Lorain, Medina, Portage, and Summit counties. EPA is also approving, as a revision to the Ohio State Implementation Plan (SIP), the state’s plan for maintaining the 2008 ozone standard through 2030 in the Cleveland area. Finally, EPA finds adequate and is approving the state’s 2020 and 2030 volatile organic compound (VOC) and oxides of nitrogen (NO_x) Motor Vehicle Emission Budgets (MVEBs) for the Cleveland area. The Ohio Environmental Protection Agency (Ohio EPA) submitted the SIP revision and redesignation request on July 6, 2016.

DATES: This final rule is effective January 6, 2017.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2016–0396. All documents in the docket are listed in the <http://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through <http://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Jenny Liljegren, Physical Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18)),