most recent fiscal year. Regardless of whether this proposed enforcement policy is adopted in any form, the EAS program contains certain statutory protections that an adversely impacted EAS community may invoke. First, in the event that DOT determines that a community is ineligible because it exceeds the $200 subsidy cap provision in a given fiscal year, the community may petition the Secretary of DOT for a waiver pursuant to Pubic Law 112–97, Sec. 426(e) (c) (Feb. 14, 2012). Under this provision, ''[s]ubject to the availability of funds, the Secretary may waive, on a case-by-case basis, the subsidy-per-passenger cap.'' The law further provides: ''A waiver . . . shall remain in effect for a limited period of time, as determined by the Secretary.'' Second, a community that is deemed ineligible based on the $200 subsidy cap and removed from the program may petition the Secretary for reinstatement into the program in a subsequent year if the community can demonstrate that it will be able to comply with the $200 subsidy cap on an annual basis going forward.

The Department seeks comments from all interested parties regarding this proposed enforcement policy.

Issued in Washington, DC, on April 23, 2014.

Brandon M. Belford,

Deputy Assistant Secretary for Aviation and International Affairs.

[FR Doc. 2014–09830 Filed 4–30–14; 8:45 am]

BILLING CODE 4910–9X–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2006–0140]

RIN 0960–AF35

Revised Medical Criteria for Evaluating Neurological Disorders; Reopening of the Comment Period

AGENCY: Social Security Administration.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: On February 25, 2014, we published in the **Federal Register** a notice of proposed rulemaking (NPRM) regarding Revised Medical Criteria for Evaluating Neurological Disorders and solicited public comments. We provided a 60-day comment period ending on April 28, 2014. We are reopening the comment period for 30 days.

DATES: The comment period for the notice of proposed rulemaking published on February 25, 2014 (79 FR 10636), is reopened. To ensure that your written comments are considered, we must receive them no later than June 2, 2014.

ADDRESSES: You may submit comments by any one of three methods—Internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2006–0140 so that we may associate your comments with the correct regulation.

CAUTION: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comments via the Internet. Please visit the Federal eRulemaking portal at *http://www.regulations.gov*. Use the *Search* function to find docket number SSA–2006–0140. The system will issue you a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. *Fax:* Fax comments to (410) 966–2830.

3. *Mail:* Address your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 3100 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at *http://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Cheryl Williams, Office of Medical Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1020. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION: This document reopens to June 2, 2014, the comment period for the notice of proposed rulemaking that we published on February 25, 2014. We are reopening the comment period in light of the comments that we have received on the proposed rules. If you have already provided comments on the proposed rules, we will consider your comments and you do not need to resubmit them.

Dated: April 25, 2014.

Carolyn W. Colvin,

Acting Commissioner of Social Security.

[FR Doc. 2014–09951 Filed 4–30–14; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2014–N–0297]

Reclassification of Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair and Surgical Instrumentation for Urogynecologic Surgical Mesh Procedures; Designation of Special Controls for Urogynecologic Surgical Mesh Instrumentation

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is proposing to reclassify surgical mesh for transvaginal pelvic organ prolapse (POP) repair from class II to class III. FDA is proposing this reclassification based on the tentative determination that general controls and special controls together are not sufficient to provide reasonable assurance of safety and effectiveness for this device. In addition, FDA is proposing to reclassify urogynecologic surgical mesh instrumentation from class I to class II. The Agency is also proposing to establish special controls for surgical instrumentation for use with urogynecologic surgical mesh. FDA is proposing this action, based on the tentative determination that general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of these devices, and there is sufficient information to establish special controls to provide such assurance. The Agency is reclassifying both the surgical mesh for transvaginal repair and the urogynecologic surgical mesh instrumentation on its own initiative based on new information.

DATES: Submit either electronic or written comments on this proposed order by July 30, 2014. Please see section XIII for the proposed effective date of any final order that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2014–N–0297, 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 Agency name and Docket No. FDA–2014–N–0297 for this rulemaking. 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: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1646, Silver Spring, MD 20993, 301–796–5616, *melissa.burns@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) establishes 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.

Section 513(a)(1) of the FD&C Act defines three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under sections 501, 502, 510, 516, 518, 519, or 520 of the FD&C Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j), or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use that is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act). Class II devices are those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the issuance of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act; see also § 860.3(c)(2) (21 CFR 860.3(c)(2))). Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide reasonable assurance of safety and effectiveness, and are purported or represented for a use in supporting or sustaining human life or for a use that is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Section 513(e)(1) 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) 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* 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 regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard,* supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F. Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science'' (See *Upjohn* v. *Finch,* supra, 422 F.2d at 951.). Whether data before the Agency are past or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in § 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. 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).

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final reclassification 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 to a public docket. FDA has held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to surgical mesh for transvaginal POP repair and, therefore, has met this requirement under section 513(e)(1) of the FD&C Act. As explained further in section VIII, a meeting of a device classification panel described in section 513(b) of the FD&C Act took place in 2011 to discuss whether surgical mesh for transvaginal POP repair should be reclassified to class III or remain in class II, and the panel recommended that the device be reclassified into class III because general controls and special controls would not be sufficient to provide a reasonable assurance of safety and effectiveness. FDA is not aware of new information since the 2011 panel that would provide a basis for a different recommendation or findings. The 2011 panel meeting did not include a specific discussion of surgical instrumentation for use with urogynecologic surgical mesh and hence FDA will convene a panel to discuss this issue prior to finalizing reclassification of instrumentation for this use.

Section 513(e)(1)(A)(i) of the FD&C Act requires that the proposed reclassification order 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; the nature and if known, incidence of the risk of the device; and in the case of reclassification from class II to class III, why general controls and special controls together are not sufficient to provide reasonable assurance of safety and effectiveness for the device.

In accordance with section 513(e)(1), the Agency is proposing, based on new information that has come to the Agency's attention since the original classification of surgical mesh, to reclassify surgical mesh for transvaginal POP repair, based on the tentative determination that general controls and special controls are not sufficient to provide a reasonable assurance of safety and effectiveness. Also, the Agency is proposing, based on new information, to reclassify urogynecologic surgical mesh instrumentation from class I to class II, and as part of the proposed reclassification and consistent with section 513(a)(1)(B), is proposing to establish special controls for urogynecologic surgical mesh instrumentation. FDA tentatively determines that the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of this instrumentation, and there is sufficient information to establish special controls to provide such assurance. FDA is proposing reclassification of both devices based on its review of information received through multiple sources. These sources include: (1) Postmarket surveillance of medical device reports (MDRs), (2) concerns raised by the clinical community and citizens, and (3) the published literature.

Section 515(b) of the FD&C Act (21 U.S.C. 360e) provides that for any class III preamendments device, FDA shall by order require such device to have approval of a PMA or notice of completion of a product development protocol (PDP). Elsewhere in this issue of the **Federal Register**, FDA is proposing to require the filing of a PMA or notice of completion of a PDP, which will only be finalized if FDA reclassifies surgical mesh for transvaginal POP repair to class III.

II. Regulatory History of the Devices

Surgical mesh is a preamendments device classified into class II (§ 878.3300 (21 CFR 878.3300)). Beginning in 1992, FDA cleared premarket notification (510(k)) submissions for surgical mesh indicated for POP repair under the general surgical mesh classification regulation, § 878.3300. FDA has cleared over 100 510(k) submissions for surgical meshes with a POP indication. Urogynecologic surgical mesh instrumentation is currently classified as a class I device under § 876.4730 (21 CFR 876.4730) (manual gastroenterology-urology surgical instrument and accessories) or § 878.4800 (manual surgical instrument for general use).

III. Device Description

Surgical mesh can be placed abdominally or transvaginally to repair POP. When placed transvaginally, surgical mesh can be placed in the anterior vaginal wall to aid in the correction of cystocele (anterior repair), in the posterior vaginal wall to aid in correction of rectocele (posterior repair), or attached to the vaginal wall and pelvic floor ligaments to correct uterine prolapse or vaginal apical prolapse (apical repair). These devices are made of synthetic material, non-synthetic material, or a combination of both. They are marketed as either stand-alone mesh products or mesh kits (i.e., the product includes mesh and instrumentation to aid insertion, placement, fixation, and/or anchoring).

This proposed order does not include surgical mesh indicated for surgical treatment of stress urinary incontinence, sacrocolpopexy (transabdominal POP repair), hernia repair, and other non-urogynecologic indications.

Many mesh products include instrumentation specifically designed to aid in insertion, placement, fixation, and anchoring of the mesh in the body. Instrumentation can also be provided separately from the mesh implant. This instrumentation is typically composed of a stainless-steel needle attached to a plastic handle and is similar to trocar needles used in general surgery. The needles used in mesh-augmented urogynecologic repair are designed to aid transvaginal or transabdominal insertion and placement of the mesh. Instrumentation for mesh-augmented POP repair can also be designed for a specific anatomical compartment.

IV. Proposed Reclassification

FDA is proposing that surgical mesh for transvaginal POP repair be reclassified from class II to class III. FDA is also proposing that urogynecologic surgical mesh instrumentation be reclassified from class I to class II with special controls. In accordance with sections 513(e)(1) of the FD&C Act, FDA, on its own initiative, is proposing to reclassify these devices based on new information.

V. Dates New Requirements Apply

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. If FDA finalizes this order, surgical mesh for transvaginal POP repair will be reclassified into class III and urogynecologic surgical mesh instrumentation will be reclassified into class II with special controls.

VI. Public Health Benefits and Risks to Health

As required by section 513(e)(1)(A)(I) of the FD&C Act, FDA is providing a substantive summary of the valid scientific evidence regarding the public health benefit of the use of surgical mesh for transvaginal POP repair and urogynecologic surgical mesh instrumentation, and the nature and, if known, incidence of the risk of the devices.

The devices have the potential to benefit the public health by aiding in the correction of cystocele (anterior repair), rectocele (posterior repair), uterine prolapse, and vaginal apical prolapse (apical repair).

FDA has evaluated the risks to health associated with the use of surgical mesh indicated for transvaginal POP repair and has identified the following risks for this device:

1. Perioperative risks. Organ perforation or injury and bleeding (including hemorrhage/hematoma).

2. Vaginal mesh exposure (mesh visualized through the vaginal epithelium, e.g., separated incision line) (Ref. 1). Clinical sequelae include pelvic pain, infection, de novo dyspareunia (painful sex for patient or partner), de novo vaginal bleeding, atypical vaginal discharge, and the need for additional corrective surgeries (possibly including mesh excision).

3. Mesh extrusion (passage of mesh into visceral organ, including the bladder or rectum) (Ref. 1). Clinical sequelae include pelvic pain, infection, de novo dyspareunia, fistula formation, and the need for additional corrective surgeries (possibly including suprapubic catheter, diverting colostomy).

4. Other risks that can occur without mesh exposure or extrusion include vaginal scarring, shrinkage, and tightening (possibly caused by mesh/tissue contraction); pelvic pain; infection (including pelvic abscess); de novo dyspareunia; de novo voiding dysfunction (e.g., incontinence); recurrent prolapse; and neuromuscular problems (including groin and leg pain).

FDA has also evaluated the risks to health associated with the use of urogynecologic surgical mesh instrumentation and has identified the following risks for this device:

1. Perioperative risks. Organ perforation or injury and bleeding (including hemorrhage/hematoma).

2. Damage to blood vessels, nerves, connective tissue, and other structures. This may be caused by improperly designed and/or misused surgical mesh instrumentation. Clinical sequelae include pelvic pain and neuromuscular problems.

3. Adverse tissue reaction. This may be caused by non-biocompatible materials.

4. Infection. This may be due to inadequate sterilization and/or reprocessing instructions or procedures.

As discussed further in this document, these findings regarding the public health benefits and risks to health associated with surgical mesh for transvaginal POP repair and urogynecologic surgical mesh instrumentation are based on publicly available information, including the published literature and MDRs, and are supported by the reports and recommendations of the Obstetrics and Gynecological Devices Panel (the Panel) from the meeting on September 8 and 9, 2011.

VII. Summary of the Data Upon Which the Reclassification Is Based

A. Safety of Surgical Mesh Used for Transvaginal Repair of Pelvic Organ Prolapse

In the published literature, mesh exposure (also referred to as erosion or extrusion in the published literature) is the most common and consistently reported mesh-related complication following transvaginal POP repair with mesh. In this document, we use the term ''mesh exposure'' to refer to mesh visualized through the vaginal epithelium, and we use the term ''mesh extrusion'' to refer to passage of mesh into a visceral organ, including into the bladder or rectum.

Mesh exposure can result in serious complications unique to mesh procedures and is not experienced by patients who undergo traditional repair. Mesh exposure may require mesh removal or excision to manage the sequelae (e.g., pelvic pain, infection (including pelvic abscess), and dyspareunia). This complication can be life altering for some women as mesh removal or excision may require multiple surgeries and sequelae may persist despite mesh removal (Ref. 2). Other clinical sequelae associated with mesh exposure include vaginal bleeding and vaginal discharge (Refs. 2 and 3).

Less common is mesh extrusion partly or through the bladder or rectal mucosa (Ref. 4). In addition to the clinical sequelae previously described, the former may require a suprapubic catheter (Ref. 4), and when the latter occurs ''a diverting colostomy may be needed to excise and repair the erosion site and lead[s] to life-long morbidity for the patient'' (Ref. 5).

A 2011 systematic review of the safety of transvaginal POP repair with mesh by Abed et al. cited a summary incidence of mesh exposure of 10.3 percent (95 percent CI, 9.7–10.9 percent; range 0–29.7 percent within 12 months of surgery from 110 studies including 11,785 women in whom mesh was used for transvaginal POP repair) (Ref. 3). The incidence of mesh exposure did not differ between nonabsorbable synthetic mesh (10.3 percent) and biologic graft material (10.1 percent) (Ref. 3).

For non-absorbable synthetic mesh exposures, 56 percent (448/795) of patients required surgical excision in the operating room with some women requiring two to three additional surgeries (Ref. 3). The one randomized controlled trial (RCT) with available long-term outcomes of anterior repair with nonabsorbable synthetic mesh found that 5 percent of patients had unresolved mesh exposure at 3 years of followup (Ref. 6).

Less information is available about management of exposure from biologic grafts. The review by Abed et al. found that, for the 35 women in which management of exposure from biologic grafts was discussed, half responded to local treatment with topical agents. For the remainder, management of the exposure was not discussed (Ref. 3).

Mesh/tissue contraction, causing vaginal scarring, shrinkage, tightening, and/or pain in association with transvaginal POP repair with mesh, is another mesh-specific adverse event that has been reported in the literature (Refs. 7 and 8). However, vaginal scarring, shrinkage, and tightening can also occur following traditional repair.

Other postoperative adverse events commonly reported in the literature that are associated with POP repair with mesh are pelvic pain, infection, de novo dyspareunia, de novo voiding dysfunction (e.g., incontinence), neuromuscular problems (including groin and leg pain), and additional corrective surgeries for complications or recurrent prolapse (Refs. 2, 7, 9, 10).

These adverse events are not unique to POP procedures with mesh, but repeat surgery for complications appears to be highest for transvaginal POP repair with mesh, followed by sacrocolpopexy and traditional repair (Refs. 11 and 12). A systematic review of re-surgery rates following POP repair found that transvaginal surgery with mesh is associated with a higher rate of complications requiring reoperation compared to sacrocolpopexy (abdominal POP repair with mesh) or traditional transvaginal repair (7.2 percent vs. 4.8 percent vs. 1.9 percent, respectively) (Ref. 11). (For transvaginal surgery with mesh, 24 studies including 3,425 women with mean followup of 17 months were included in this systematic review. For sacrocolpopexy, 52 studies including 5,639 women with mean followup of 26 months were included, and for traditional transvaginal repair, 48 studies including 7,827 women with mean followup of 32 months were included.) From the one RCT that directly compared sacrocolpopexy to transvaginal POP repair with mesh (both using synthetic nonabsorbable mesh), overall re-surgery within 2 years postoperative was significantly more common following transvaginal POP repair with mesh than laparoscopic sacrocolpopexy, with rates of 22 percent (12/55) and 5 percent (3/53), respectively (p=0.006) (Ref. 12). De novo

stress urinary incontinence has been reported to occur more frequently following anterior repair with mesh compared to traditional anterior repair (Ref. 13). Currently, there is no evidence in the literature that other postoperative adverse events occur more commonly following mesh repairs compared to non-mesh repairs.

The findings within the literature are consistent with the types and relative frequency of adverse events that have been reported to FDA through the Manufacturer and User Facility Device Experience (MAUDE) database. Between January 1, 2011, and December 31, 2013, FDA received 19,043 adverse events for surgical mesh used for POP repair. The most frequently reported adverse events were pain, erosion, and injury. Further discussion of the risks associated with surgical mesh for transvaginal POP repair is provided in FDA materials for the September 2011 panel meeting (Ref. 14).

B. Effectiveness of Surgical Mesh Used for Transvaginal Repair of Pelvic Organ Prolapse

The majority of trials evaluating effectiveness of POP repair use a primary effectiveness outcome of ideal anatomic support, defined as prolapse Stage 0 or 1 (i.e., the lowest point of prolapse is more than 1 cm proximal to the vaginal opening) on the Pelvic Organ Prolapse Quantification (POP–Q) scale. This outcome measure was chosen as a means to provide a quantitative description of the degree of prolapse, but it is not correlated with POP symptoms or patient assessment of improvement (Ref. 15). Additionally, assessment of prolapse stage suffers from interobserver variability (Ref. 16).

The published literature reveals that, although transvaginal POP repair with mesh often restores anatomy, it has not been shown to improve clinical benefit over traditional non-mesh repair and, given the risks associated with mesh, the probable benefits from use of the device do not outweigh the probable risks. This is particularly true for apical and posterior repair with mesh (Refs. 9, 10, 17–22).

A systematic review of transvaginal mesh kits for apical repair found that they appear effective in restoring apical prolapse in the short term, but long-term outcomes are unknown (Ref. 23). Additionally, there is no evidence that transvaginal apical repair with mesh is more effective than traditional transvaginal apical repair. Specifically, only two RCTs have evaluated apical repair with mesh compared to traditional transvaginal repair, and neither found a significant improvement in anatomic outcome with mesh augmentation (Refs. 17 and 18). Both of these RCTs evaluated synthetic nonabsorbable transvaginal mesh kits for multicompartment repair (i.e., anterior, posterior, or total (anterior and posterior) mesh placement). Of these two trials, Withagen et al. reported an anatomic benefit in the posterior compartment following posterior repair with mesh, but subjects in the trial who underwent posterior repair with mesh had less posterior prolapse at baseline than subjects who underwent traditional repair (Ref. 18). Therefore, the mesh arm of the Withagen et al. study was less ''challenged'' than the non-mesh arm. Iglesia et al. did not show an anatomic benefit in the posterior compartment following posterior repair with mesh augmentation (Ref. 17).

The only RCT to compare posterior repair with mesh to traditional posterior repair (without multiple compartment repair) showed that subjects who underwent repair using a synthetic absorbable mesh had worse anatomic outcomes than those who underwent traditional repair (Ref. 19). Two other RCTs that compared combined anterior and posterior repair with mesh to traditional anterior and posterior repair found no additional anatomic benefit to mesh augmentation in the posterior compartment (Refs. 19 and 20). One of these used a synthetic absorbable mesh (Ref. 19) and the other used a synthetic nonabsorbable mesh (Ref. 20).

A 2010 review of management of posterior vaginal wall repair by Kudish and Iglesia states ''studies published to date do not support use of biologic or synthetic absorbable grafts in reconstructive surgical procedures of the posterior compartment as these repairs have not improved anatomic or functional outcomes over traditional posterior [repair]'' (Ref. 5). At the time of publication of this review, no studies comparing posterior repair with synthetic non-absorbable mesh to traditional posterior repair had been performed. However, as noted previously, reported outcomes in the three trials in which synthetic non-absorbable mesh was used in the posterior compartment (Refs. 17, 18, 20) were generally consistent with the conclusions of Kudish and Iglesia (Ref. 5). These authors also note that, when erosion of vaginal mesh occurs in the posterior compartment, it often requires excision of exposed mesh.

The literature does suggest that there may be an anatomic benefit to anterior repair with mesh augmentation (Refs. 6, 9, 10, 13, 18, 19, 22, 24–30); however, there are significant limitations in the available data. The majority of the trials that showed an anatomic benefit to anterior repair with mesh augmentation compared to traditional repair used synthetic non-absorbable mesh, but only one used a synthetic absorbable material (Ref. 19) and one used a non-synthetic material (Ref. 28). Therefore, these results may not be generalizable to all mesh types. Only 2 of 11 peer-reviewed publications on anterior prolapse repair were evaluator-blinded prospective RCTs (Refs. 20, 27) such that evaluator bias was minimized, and these two RCTs reached different conclusions. One showed no anatomical improvement for the mesh cohort compared to the traditional non-mesh repair cohort (Ref. 20). The second evaluator-blinded RCT did show an anatomic benefit for mesh in the anterior compartment, but this RCT was a single-center, single-investigator study (Ref. 27). Therefore, the outcomes from this study may not be representative of procedures performed at other centers by other operators.

Although multiple trials reported in the literature report a benefit to POP repair with mesh compared to traditional repair, these trials were designed to evaluate an endpoint indicative of ideal anatomic support, rather than an outcome more representative of improvement in patient symptoms. A re-analysis of one RCT comparing three techniques for anterior repair (two without mesh and one with synthetic absorbable mesh augmentation) showed no differences in effectiveness across all study groups when less stringent (and arguably, more clinically meaningful) criterion for success, defined as prolapse at or above the vaginal opening, was applied (Ref. 31). The original trial defined recurrent prolapse as greater than Stage 1 at 1 year postimplant and, using this definition, had concluded that subjects who had anterior repair with mesh augmentation were less likely to have recurrent prolapse.

Additionally, patients who undergo traditional repair have equivalent improvement in quality of life (Refs. 20, 22, 27, 32) compared to patients who undergo transvaginal POP repair with mesh. The differential in reported success rates between mesh and non-mesh repairs is not reflected in the comparison of quality of life outcomes where no difference was observed, indicating that use of a non-symptom related outcome measure (i.e., ideal pelvic support determined by POP–Q) likely accounts for this differential.

C. Safety and Effectiveness of Surgical Instrumentation for Use With Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair and Other Urogynecologic Procedures

Implantation of surgical mesh for urogynecologic procedures, such as POP repair, is a complex procedure, and specialized surgical instrumentation has been developed to aid the insertion, placement, fixation, and anchoring of the surgical mesh. The procedure is performed ''blind,'' such that the surgeon cannot directly visualize placement of the surgical mesh, and is reliant on the surgical instrumentation, palpation of anatomic landmarks, and experience for accessing critical ligaments and attaching anchors and other devices needed to secure the mesh. Because adverse events related to surgical mesh are typically submitted with reference to the product code for the mesh itself, it is difficult to distinguish adverse events related to the surgical instrumentation from those directly related to the surgical mesh. However, as was discussed by the Panel (see section VIII), there is a concern that the use of surgical instrumentation, such as long trocars, can result in significant adverse events to patients. From January 1, 2011, to December 31, 2013, FDA received 843 reports related to bleeding, hematoma, and blood loss, 42 reports related to organ perforation, and 196 reports of neuromuscular problems through the MAUDE database for surgical mesh indicated for POP. In addition, clinical studies, case reports, and systematic literature reviews in the published literature have reported similar perioperative adverse events (Refs. 7, 9, 11–13, 17, 18, 22, 24–25, 29). Given the nature of these adverse events, it is reasonable to assume that they were caused by or related to the use of instrumentation to insert, place, fix, or anchor the surgical mesh perioperatively.

In addition, use of surgical instrumentation may lead to adverse tissue reaction as a result of using non-biocompatible materials. It may also lead to infection due to inadequate sterilization, inadequate reprocessing procedures, or use beyond the labeled expiration date. These are general risks that apply to devices that have patient contact, are provided sterile, and are reusable.

FDA tentatively concludes that appropriately designed and labeled instrumentation is critical to the safe and effective use of surgical mesh for female urological and gynecological procedures, and that surgical instrumentation for this use must be adequately tested prior to marketing.

VIII. 2011 Classification Panel Meeting

In October 2008, as a result of over 1,000 adverse events received, FDA issued a Public Health Notification (PHN) informing clinicians and their patients of the adverse event findings related to use of urogynecologic surgical mesh (Ref. 33). The PHN also provided recommendations for clinicians on how to mitigate the risks associated with these devices and information for their patients. On July 13, 2011, based on an updated adverse event search, FDA issued a Safety Communication titled ''UPDATE on Serious Complications Associated With Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse'' (Ref. 34). On the same date, FDA also issued a white paper titled ''Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse'' (Ref. 35). The continued reports of adverse events also prompted FDA to consider the information available regarding the use of surgical mesh for transvaginal POP repair and to evaluate whether the classification of this device type should be reconsidered.

In accordance with section 513(e)(1) of the FD&C Act and 21 CFR part 860, subpart C, on September 8 and 9, 2011, FDA referred the proposed reclassification to the Panel for its recommendations on the proposed change in the device's classification from class II to class III, among other related questions (Ref. 14). The Panel consensus was that a favorable benefit-risk profile for surgical mesh used for transvaginal POP repair has not been well established. The Panel discussed the number of serious adverse events associated with the use of these devices and concluded that their safety is in question. In addition, the Panel consensus was that the effectiveness of surgical mesh for transvaginal POP repair has not been well established, and the device may not be more effective for this use than traditional non-mesh surgery, especially for the apical and posterior vaginal compartments.

The Panel consensus was that premarket clinical data are needed for surgical mesh for transvaginal POP repair. The majority of panel members recommended that these devices be evaluated against a control arm of traditional ''native-tissue'' (nonmesh) repair to demonstrate a reasonable assurance of safety and effectiveness for the devices. Panel members also emphasized that these studies should evaluate both anatomic outcomes and patient satisfaction and that the duration of followup should be at least 1 year, with additional followup in a postmarket setting.

The Panel's consensus was that each individual mesh device should undergo a comparison to native tissue repair in order to establish a reasonable assurance of safety and effectiveness. The Panel's consensus was that general controls and special controls together would not be sufficient to provide reasonable assurance of the safety and effectiveness of surgical mesh indicated for transvaginal POP repair, and that these devices should be reclassified from class II to class III. Panel members also expressed concern that the use of surgical instrumentation, such as long trocars, can result in significant adverse events to patients.

Panel members also concluded that manufacturers of surgical mesh indicated for transvaginal POP repair should conduct postmarket studies of currently marketed devices. Beginning on January 3, 2012, FDA issued postmarket surveillance study orders to manufacturers under section 522 of the FD&C Act (21 U.S.C. 360*l*) (''section 522 orders'') for transvaginal POP mesh products that are already legally marketed. As of the date of this order, FDA had issued 126 section 522 orders to 33 manufacturers of transvaginal POP mesh products.

The Panel also emphasized that additional work should be focused on patient labeling and informed consent, including providing benefit-risk information on available treatment options for POP—surgical and nonsurgical options—so patients understand long-term safety and effectiveness outcomes. Panel members also recommended mandatory registration of implanted devices, as well as surgeon training and credentialing. They encouraged FDA to work with other stakeholders, such as clinical professional organizations and industry, and to use existing databases and new data collection tools (e.g., registries) to develop a meaningful database on postmarket clinical outcomes.

IX. Summary of Reasons for Reclassification

Based on the information reviewed by FDA relating to the safety and effectiveness of surgical mesh for transvaginal POP repair, including the valid scientific evidence discussed in section VII, FDA tentatively concludes that surgical mesh for transvaginal POP repair should be reclassified from class II to class III. As established in section

513(a)(1)(C) of the FD&C Act and § 860.3(c)(3), a device is in class III if insufficient information exists to determine that general controls and special controls together are sufficient to provide reasonable assurance of its safety and effectiveness and the device is purported or represented to be for a use that is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury. FDA tentatively agrees with the Panel consensus that the safety and effectiveness of this device type has not been established and that these devices should be evaluated in clinical studies that compare the device to native tissue repair in order to establish a reasonable assurance of safety and effectiveness. Therefore, FDA tentatively concludes that general and special controls together are not sufficient to provide a reasonable assurance of the safety and effectiveness of surgical mesh intended for transvaginal POP repair. In addition, in the absence of an established positive benefit-risk profile, the risks to health associated with the use of surgical mesh for transvaginal POP repair identified previously present a potential unreasonable risk of illness or injury.

Based on FDA's tentative determination that general controls and special controls together are not sufficient to provide reasonable assurance of safety and effectiveness of surgical mesh intended for transvaginal POP repair and that the device presents a potential unreasonable risk of illness or injury, FDA proposes to reclassify surgical mesh for transvaginal POP repair from class II to class III.

The procedure for implanting surgical mesh typically involves use of surgical instrumentation, some of which is specifically designed and labeled for urogynecologic procedures, including transvaginal POP procedures. Instrumentation for this use is currently classified under existing regulations for class I devices, including § 876.4730 (manual gastroenterology-urology surgical instrument and accessories) or § 878.4800 (manual surgical instrument for general use).

FDA tentatively concludes that valid scientific evidence demonstrates that special controls, in addition to the general controls, are necessary to provide a reasonable assurance of safety and effectiveness for surgical instrumentation used for implanting surgical mesh for urogynecological use.

Therefore, FDA proposes to reclassify instrumentation used for implanting surgical mesh for urogynecological use from class I to class II (special controls). If the proposed reclassification is finalized, a premarket notification submission that addresses, among other things, the special controls established for the device, would be required prior to marketing the device.

X. Special Controls

FDA tentatively concludes that the following special controls, in addition to general controls, are sufficient to mitigate the risks to health described in section VI attributable to the surgical instrumentation for implanting surgical mesh for urogynecological procedures:

- The device must be demonstrated to be biocompatible;
- The device must be demonstrated to be sterile;
- Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the requested shelf life;
- Bench and/or cadaver testing must demonstrate safety and effectiveness in expected-use conditions; and
- Labeling must include:
  - Information regarding the mesh design that may be used with the device;
  - Detailed summary of the clinical evaluations pertinent to use of the device;
  - Expiration date; and
  - 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.

Table 1 shows how the risks to health identified in section VI associated with urogynecological surgical mesh instrumentation can be mitigated by the proposed special controls.

TABLE 1—HEALTH RISK AND MITIGATION MEASURE FOR UROGYNECOLOGICAL SURGICAL MESH INSTRUMENTATION

Identified risk	Special controls
Perioperative Injury ...	Bench and/or Cadaver Testing. Labeling. Shelf Life Testing.
Pelvic Pain and Neuromuscular Problems.	Bench and/or Cadaver Testing. Shelf Life Testing. Labeling.
Infection	Sterilization Validation. Shelf Life Testing. Labeling
Adverse Tissue Reaction.	Biocompatibility.

FDA believes that bench and/or cadaver testing can help ensure that urogynecologic surgical mesh instrumentation is appropriately designed and limits damage to blood vessels, nerves, connective tissue, and other structures. Also, such evaluation may help limit the adverse events, such as perioperative injury (organ perforation or injury and bleeding), pelvic pain, and neuromuscular problems, reported to the MAUDE database and described in the published literature as discussed in section VII. In addition, labeling specifying the mesh type that may be used with the device and provision of a detailed summary of the clinical evaluations pertinent to use of the device will also mitigate these risks. Lastly, shelf life testing demonstrating that the device maintains its functionality over the duration of its shelf life will also mitigate damage to blood vessels, nerves, connective tissue, and other structures, and perioperative risks.

Also, the risk of adverse tissue reaction as a result of using non-biocompatible materials can be mitigated by biocompatibility testing. FDA finds 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. In addition, FDA believes that shelf life testing and inclusion of an expiration date on the labeling will mitigate the risk of infection by ensuring that the device maintains its sterility over the duration of its shelf life. The expiration date may prevent use of the device after its validated shelf life.

FDA clarifies here that these special controls are specific to surgical instrumentation specifically intended to be used with surgical mesh for urogynecological procedures. FDA intends to evaluate instrumentation provided with a mesh kit as part of the review of that surgical mesh.

In addition, the surgical instrumentation used for implanting surgical mesh for urogynecological procedures are prescription devices within the meaning of 21 CFR 801.109.

XI. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this proposed reclassification 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.

XII. Paperwork Reduction Act of 1995

This proposed 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; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information under 21 CFR part 822 have been approved under OMB control number 0910–0449; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

XIII. 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.

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. Section 513(e) as amended requires FDA to issue a final order rather than a regulation. FDA will codify reclassifications resulting from changes issued in final orders 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 proposed order we are proposing to codify the reclassification of surgical mesh for transvaginal pelvic organ prolapse repair into class III and proposing to codify the reclassification of specialized surgical instrumentation for use with urogynecologic surgical mesh devices into class II (special controls).

XV. Comments

Interested persons may submit either electronic comments regarding this proposed order 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.*

XVI. References

FDA has placed the following references on display in the Division of Dockets Management (see **ADDRESSES**). Interested persons may see them between 9 a.m. and 4 p.m., Monday through Friday, and online at *http://www.regulations.gov.* (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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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, it is proposed that 21 CFR part 884 be amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 1. The authority citation for 21 CFR 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.* Surgical instrumentation for use with surgical mesh for urogynecological procedures is a prescription device used to aid in insertion, placement, fixation, or anchoring of surgical mesh for procedures including transvaginal pelvic organ prolapse repair, sacrocolpopexy (transabdominal pelvic organ prolapse repair), and treatment of female stress urinary incontinence. Examples of such surgical instrumentation include needle passers and trocars, needle guides, fixation tools, and tissue anchors. This device does not include manual gastroenterology-urology surgical instrument and accessories (§ 876.4730) nor manual surgical instrument for general use (§ 878.4800).

(b) *Classification.* Class II (special controls). The special controls for this device are:

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

(2) The device must be demonstrated to be sterile;

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

(4) Bench and/or cadaver testing must demonstrate safety and effectiveness in expected-use conditions; 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.

■ 3. Add § 884.5980 to Subpart F to read as follows:

§ 884.5980 Surgical mesh for transvaginal pelvic organ prolapse repair.

(a) *Identification.* Surgical mesh for transvaginal pelvic organ prolapse repair is a prescription device intended to reinforce soft tissue in the pelvic floor. This device is a porous implant that is synthetic, non-synthetic, or both. This device does not include surgical mesh for other intended uses (§ 878.3300).

(b) *Classification.* Class III (premarket approval).

Dated: April 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09907 Filed 4–29–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2014–N–0298]

Effective Date of Requirement for Premarket Approval for Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a proposed administrative order to require the filing of a premarket approval application (PMA) if the surgical mesh for transvaginal pelvic organ prolapse (POP) repair device is reclassified from class II to class III. The Agency is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the statute's PMA requirements and the benefit to the public from the use of the device.

DATES: Submit either electronic or written comments on this proposed order by July 30, 2014. FDA intends that, if a final order based on this proposed order is issued, anyone who wishes to continue to market the device will need to submit a PMA within 90 days of the effective date of the final order or on the last day of the 30th