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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2011–N–0118]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Hemorrhoid Prevention Pressure Wedge

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the hemorrhoid prevention pressure wedge into class II (special controls). The special controls will apply to the device in order to provide a reasonable assurance of safety and effectiveness of the device. A hemorrhoid prevention pressure wedge provides support to the perianal region during the labor and delivery process.

DATES: This rule is effective May 16, 2011. The classification was applicable on January 13, 2011.

FOR FURTHER INFORMATION CONTACT: Glenn Bell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G112, Silver Spring, MD 20993–0002, 301–796–6531.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C.360c(i)), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA will, within 60 days of receiving this request, classify the device by written order. This classification will be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on August 5, 2009, classifying the Hem-Avert Perianal Stabilizer into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On August 17, 2009, Plexus Biomedical, Inc., submitted a petition requesting classification of the Hem-Avert Perianal Stabilizer under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II. (Ref. 1)

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name hemorrhoid prevention pressure wedge, and it is identified as a hemorrhoid prevention pressure wedge that provides mechanical support to the perianal region during the labor and delivery process. External mechanical support of the perianal region is intended to help prevent the occurrence of external hemorrhoids associated with vaginal childbirth.

FDA has identified the following risks to health associated specifically with this type of device and the recommended measures to mitigate these risks.

TABLE 1—HEALTH RISKS AND MITIGATIONS

Identified risk	Mitigation measures
Skin/tissue trauma (*e.g.,* rectal and/or anal trauma, necrosis, thinning, abrasion, laceration to the perineum, vulvar hematoma, sloughing)	Nonclinical Analysis and Testing. Clinical Information. Labeling.
Device failure (*e.g.,* material failure, slippage)	Nonclinical Analysis and Testing. Labeling.
Device failure—obstruction to the treatment area caused by inability to remove the instrument quickly	Device Description. Labeling.
Infection	Labeling.
Adverse tissue reaction	Biocompatibility.
Pain	Nonclinical Analysis and Testing. Biocompatibility.

FDA believes that the following special controls address the risks to health and provide reasonable assurance of the safety and effectiveness of the device: (1) The sale, distribution, and use of this device are restricted to

prescription use in accordance with 21 CFR 801.109; (2) the labeling should include specific instructions regarding the proper placement and use of the device; (3) the device should be demonstrated to be biocompatible; (4) mechanical bench testing of material strength should demonstrate that the device will withstand forces encountered during use; and (5) safety and effectiveness data should demonstrate that the device prevents hemorrhoids in women undergoing spontaneous vaginal delivery, in addition to general controls. Therefore, on January 13, 2011 (corrected order sent to petitioner on February 1, 2011), FDA issued an order to the petitioner classifying the device into class II. FDA is codifying the classification of the device by adding § 884.5200.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a hemorrhoid prevention pressure wedge will need to address the issues covered in the special controls.

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. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the hemorrhoid prevention pressure wedge they intend to market.

II. 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of this device from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain state requirements "different from or in addition to" certain Federal requirements applicable to devices. (21 U.S.C. 360k); *See Medtronic* v. *Lohr,* 518 U.S. 470 (1996); *Riegel* v. *Medtronic, Inc.,* 552 U.S. 312 (2008). The special controls established by this final rule create "requirements" to address each identified risk to health presented by these specific medical devices under 21 U.S.C. 360k, even though product sponsors may have flexibility in how they meet these requirements. Cf. *Papike* v. *Tambrands, Inc.,* 107 F.3d 737, 740–42 (9th Cir. 1997).

V. Paperwork Reduction Act of 1995

This final rule establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 32501–3520). The collections of information in part 807, regarding premarket notification submissions, have been approved under OMB control no. 0910–0120; the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control no. 0910–0485.

VI. References

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Plexus Biomedical, Inc., August 17, 2009.

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 21 CFR part 884 continues to read as follows:

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

■ 2. Section 884.5200 is added to subpart F to read as follows:

§ 884.5200 Hemorrhoid prevention pressure wedge.

(a) *Identification.* A hemorrhoid prevention pressure wedge provides mechanical support to the perianal region during the labor and delivery process. External mechanical support of the perianal region is intended to help prevent the occurrence of external hemorrhoids associated with vaginal childbirth.

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

(1) The sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter.

(2) The labeling must include specific instructions regarding the proper placement and use of the device.

(3) The device must be demonstrated to be biocompatible.

(4) Mechanical bench testing of material strength must demonstrate that the device will withstand forces encountered during use.

(5) Safety and effectiveness data must demonstrate that the device prevents hemorrhoids in women undergoing spontaneous vaginal delivery, in addition to general controls.

Dated: April 11, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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DEPARTMENT OF JUSTICE

28 CFR Parts 0 and 51

[CRT Docket No. 120; AG Order No. 3262–2011]

Revision of Voting Rights Procedures

AGENCY: Civil Rights Division, Department of Justice.

ACTION: Final rule.

SUMMARY: The Attorney General finds it necessary to revise the Department of Justice's "Procedures for the Administration of section 5 of the Voting Rights Act of 1965." The revisions are needed to clarify the scope of section 5 review based on recent amendments to section 5, make technical clarifications and updates, and provide better guidance to covered jurisdictions and interested members of the public concerning current Department practices. Proposed revised Procedures were published for comment on June 11, 2010, and a 60-day comment period was provided.

DATES: The rule will be effective on April 15, 2011.

FOR FURTHER INFORMATION CONTACT: T. Christian Herren, Jr., Chief, Voting Section, Civil Rights Division, United States Department of Justice, Room 7254–NWB, 950 Pennsylvania Avenue, NW., Washington, DC 20530, or by telephone at (800) 253–3931.

SUPPLEMENTARY INFORMATION:

Discussion

Section 5 of the Voting Rights Act of 1965, as amended, 42 U.S.C. 1973c, requires certain jurisdictions (listed in the Appendix) to obtain "preclearance" from either the United States District Court for the District of Columbia or the United States Attorney General before implementing any new standard, practice, or procedure that affects voting.

Procedures for the Attorney General's Administration of section 5 were first published in 1971. Proposed Procedures were published for comment on May 28, 1971 (36 FR 9781), and the final Procedures were published on September 10, 1971 (36 FR 18186). As a result of the Department's experience under the 1971 Procedures, changes mandated by the 1975 Amendments to the Voting Rights Act, and interpretations of section 5 contained in judicial decisions, proposed revised Procedures were published for comment on March 21, 1980 (45 FR 18890), and final revised Procedures were published on January 5, 1981 (46 FR 870) (corrected at 46 FR 9571, Jan. 29, 1981). As a result of further experience under the 1981 Procedures, specifically with respect to redistricting plans adopted following the 1980 Census, changes mandated by the 1982 Amendments to the Voting Rights Act, and judicial decisions in cases involving section 5, revised Procedures were published for comment on May 6, 1985 (50 FR 19122), and final revised Procedures were published on January 6, 1987 (52 FR 486).

In the twenty-four years since the previous revisions became final, the Attorney General has had further experience in the consideration of voting changes; the courts have issued a number of important decisions in cases involving section 5, and Congress enacted the 2006 amendments to the Voting Rights Act. This new revision reflects these developments.

Comments

In response to the Notice of Proposed Rulemaking ("Notice") published on June 11, 2010 (75 FR 33205), we received comments from or on behalf of two national public interest organizations, one research and educational institution, one national political organization composed of attorneys, and one individual. All comments received are available for inspection and copying at www.regulations.gov and at the Voting Section, Civil Rights Division, Department of Justice, Washington DC 20530.

The comments received expressed diverse views and were of great assistance in the preparation of these final revisions to the Procedures. The final revised Procedures reflect our consideration of the comments as well as further consideration of sections or topics that were not the subject of comments.

Section 51.2 Definitions

The purpose of the revision to the definition of "change affecting voting" or "change" is to clarify the definition of the benchmark standard, practice, or procedure. One commenter recommended we revise this section to reflect that the benchmark is the standard, practice, or procedure in force or effect at the time of the submission or the last legally enforceable standard, practice, or procedure in force or effect in the jurisdiction. We have concluded that no further revision of this section is warranted. The Voting Section's practice is to compare the proposed standard, practice, or procedure to the benchmark. Generally, the benchmark is the standard, practice, or procedure that has been: (1) Unchanged since the jurisdiction's coverage date; or (2) if changed since that date, found to comply with section 5 and "in force or effect." *Riley* v. *Kennedy,* 553 U.S. 406, 421 (2008); Procedures for the Administration of Section 5 of the Voting Rights Act of 1965, 28 CFR 51.54. Where there is an unsubmitted intervening change, the Attorney General will make no determination concerning the submitted change because of the prior unsubmitted change. In such instances, it is our practice to inform the jurisdiction there is a prior related change that has not been submitted and that simultaneous review is required. A standard, practice, or procedure that has been reviewed and determined to meet section 5 standards is considered to be in force or effect, even if the jurisdiction never implements the change because the change is effective as a matter of federal law and was available for use.

Section 51.3 Delegation of Authority

The purpose of the revisions to the delegation of authority is to make technical corrections to the delegation of authority from the Attorney General to the Assistant Attorney General, and from the Chief of the Voting Section to supervisory attorneys within the Voting Section, and to conform the Procedures to other parts of Title 28. Two commenters objected to the revisions, expressing concern that the delegation of the functions of the Chief to supervisory attorneys in the Voting Section results in the delegation of section 5 legal review authority to non-politically appointed attorneys subordinate to the Section Chief.