Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 16 and 511 are amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. In § 16.1, in paragraph (b)(2), revise the numerically sequenced entry for § 511.1(c)(1) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

(c)(1), relating to whether an investigator is eligible to receive test articles under part 511 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products; and any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

* * * * *

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

■ 3. The authority citation for part 511 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 360b, 371.

■ 4. In § 511.1:

■ a. Revise the section heading;

■ b. Revise the last sentence in paragraph (c)(1);

■ c. Add paragraphs (c)(1)(i) and (ii);

■ d. Revise the last sentence in paragraph (c)(2);

■ e. Add paragraphs (c)(2)(i) and (ii); and

■ f. Revise paragraph (c)(6).

The revisions and additions read as follows:

§ 511.1 New animal drugs for investigational use exempt from section 512(a) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

(c) * * *

(1) * * * If an explanation is offered but not accepted by the Center for Veterinary Medicine, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the question of whether the investigator is eligible to receive test articles under this part and eligible to conduct:

(i) Any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA; and

(ii) Any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

(2) * * * The notification also will explain that an investigator determined to be ineligible to receive test articles under this part will be ineligible to conduct:

(i) Any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products; and

(ii) Any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

* * * * *

(6) An investigator who has been determined to be ineligible under paragraph (c)(2) of this section may be reinstated as eligible when the Commissioner determines that the investigator has presented adequate assurances that the investigator will employ all test articles, and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA and any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug, solely in compliance with the applicable provisions of this chapter.

* * * * *

Dated: December 21, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27973 Filed 12–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2017–N–6842]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Pressure Wedge for the Reduction of Cesarean Delivery

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the pressure wedge for the reduction of cesarean delivery into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the pressure wedge for the reduction of cesarean delivery's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective December 28, 2017. The classification was applicable on December 19, 2016.

FOR FURTHER INFORMATION CONTACT: Mack Hall III, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3572, Silver Spring, MD 20993–0002, 301–796–5621, *mack.hall@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the pressure wedge for the reduction of cesarean delivery as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket

approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)). Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On January 29, 2016, Stetrix, Inc., submitted a request for De Novo classification of the Hem-Avert® Perianal Stabilizer. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 19, 2016, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 884.5210. We have named the generic type of device pressure wedge for the reduction of cesarean delivery, and it is identified as a prescription device that provides external mechanical support to the perianal region during the labor and vaginal delivery process. External mechanical support of the perianal region is intended to help reduce the occurrence of cesarean delivery.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—PRESSURE WEDGE FOR THE REDUCTION OF CESAREAN DELIVERY RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Skin/tissue trauma	Non-clinical performance data, Clinical performance data, and Labeling.
Device failure • Breakage. • Slippage.	Non-clinical performance data and Labeling.
Infection	Sterilization validation, Shelf life testing, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Pain	Labeling.
Use error	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

At the time of classification, pressure wedge for the reduction of cesarean delivery is for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

III. 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.

IV. Paperwork Reduction Act of 1995

This final order 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. 3501–3520). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

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, 360*l,* 371.

■ 2. Add § 884.5210 to subpart F to read as follows:

§ 884.5210 Pressure wedge for the reduction of cesarean delivery.

(a) *Identification.* A pressure wedge for the reduction of cesarean delivery is a prescription device that provides external mechanical support to the perianal region during the labor and vaginal delivery process. External mechanical support of the perianal region is intended to help reduce the occurrence of cesarean delivery.

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

(1) The patient contacting materials must be evaluated to be biocompatible.

(2) Nonclinical performance data must demonstrate that the device will not break when subjected to the forces it will be exposed to during labor.

(3) Performance data must validate the sterility of the device.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility and package integrity over the labeled shelf life.

(5) Clinical performance data must be provided that characterizes the rate of skin/tissue trauma.

(6) The labeling must include:

(i) Specific instructions regarding the proper placement and use of the device.

(ii) A shelf life.

Dated: December 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–28042 Filed 12–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 11

[189A2100DD/AAKC001030/A0A501010.999900]

RIN 1076–AF39

Addition of the Wind River Indian Reservation to the List of Courts of Indian Offenses

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule; confirmation.

SUMMARY: The Bureau of Indian Affairs (BIA) is confirming the interim final rule published on October 27, 2016, establishing a Court of Indian Offenses (also known as a CFR Court) for the Wind River Indian Reservation.

DATES: This final rule is effective on December 28, 2017.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth Appel, Director, Office of Regulatory Affairs & Collaborative Action—Indian Affairs, (202) 273–4680; *elizabeth.appel@bia.gov.*

SUPPLEMENTARY INFORMATION:

I. Summary of Rule
II. Procedural Requirements
A. Regulatory Planning and Review (E.O. 12866)
B. Regulatory Flexibility Act
C. Small Business Regulatory Enforcement Fairness Act
D. Unfunded Mandates Reform Act
E. Takings (E.O. 12630)
F. Federalism (E.O. 13132)
G. Civil Justice Reform (E.O. 12988)
H. Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)
I. Paperwork Reduction Act
J. National Environmental Policy Act
K. Effects on the Energy Supply (E.O. 13211)
L. Clarity of This Regulation
M. E.O. 13771: Reducing Regulation and Controlling Regulatory Costs

I. Summary of Rule

Generally, Courts of Indian Offenses operate in those areas of Indian country where Tribes retain jurisdiction over Indians that is exclusive of State jurisdiction, but where Tribal courts have not been established to fully exercise that jurisdiction. The Eastern Shoshone Tribe and the Northern Arapaho Tribe have an equal joint interest in the Wind River Indian Reservation. Since the publication of the Interim Final Rule establishing the Court of Indian Offenses for the Wind River Indian Reservation, the Shoshone & Arapaho Tribal Court has operated without the legal support of the Eastern Shoshone Tribe, and with limited resources. The Bureau has attempted to work with the Northern Arapaho Tribe towards establishing a system of courts with concurrent jurisdiction. However, after nine months of operation, the joint nature of the Wind River Indian Reservation has proven establishing such a system untenable.

Allowing the Bureau of Indian Affairs to constitute a CFR Court will provide all residents on the Wind River Indian Reservation with comprehensive judicial services, and ensure the administration of justice and public safety. To accomplish this, this rule finalizes the revision of a section of 25 CFR part 11 to add the Wind River Indian Reservation in Wyoming to the list of areas in Indian country with established Courts of Indian Offenses (also known as CFR Courts). This rule inserts the Wind River Indian Reservation into a new paragraph (d) in 25 CFR 11.100.

An interim final rule published on October 27, 2016 (81 FR 74675). Comments received on the interim final rule are addressed in Section II.H of this preamble, below.

II. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and