DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 19, 2016

Stetrix, Inc.
Mr. Mark Buchanan
President
70 Clay St.
Oakland, TN 38060

Re: DEN160005
Hem-Avert Perianal Stabilizer
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 884.5210
Regulation Name: Pressure wedge for the reduction of cesarean delivery
Regulatory Classification: Class II
Product Code: PNU
Dated: January 28, 2016
Received: January 29, 2016

Dear Mr. Buchanan,

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Hem-Avert Perianal Stabilizer, a prescription device under 21 CFR Part 801.109, for an expanded indication (new intended use) of *providing counter-pressure to the anus during vaginal childbirth, applied at 8-10 cm of dilation, to help reduce the likelihood of cesarean delivery*. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Hem-Avert Perianal Stabilizer, and substantially equivalent devices of this generic type, into class II under the generic name, Pressure wedge for the reduction of cesarean delivery.

FDA identifies this generic type of device as:

> **Pressure wedge for the reduction of cesarean delivery**. 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE

determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall 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** classifying the device type.

On January 29, 2016, FDA received your *de novo* requesting classification of the Hem-Avert Perianal Stabilizer Device into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Hem-Avert Perianal Stabilizer into class II, it is necessary that the proposed class have sufficient regulatory 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 *de novo* request, FDA has determined that the Hem-Avert Perianal Stabilizer with an expanded indication (new intended use) of *providing counter-pressure to the anus during vaginal childbirth, applied at 8-10 cm of dilation, to help reduce the likelihood of cesarean delivery* can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Method**
Skin/tissue trauma	Nonclinical performance data Clinical performance data Labeling
Device failure ▪ breakage ▪ slippage	Nonclinical performance data Labeling
Infection	Sterilization validation Shelf life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Pain	Labeling
Use error	Labeling

In combination with the general controls of the FD&C Act, the Pressure wedge for the reduction of cesarean delivery is subject to the following special controls:

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:

    a) specific instructions regarding the proper placement and use of the device
    b) a shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109. 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 type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the pressure wedge for the reduction of cesarean delivery they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Mack Hall III, Ph.D., at (301) 796-5621.

Sincerely,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health