DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. David Blurton
Chief Executive Officer
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FEB 01 2011

Re: K083692 Hem-Avert Perianal Stabilizer
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR §884.5200
Classification: II
Product Code: OOA

Dear Mr. Blurton:

This letter corrects our classification letter of January 13, 2011.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the Hem-Avert Perianal Stabilizer is a prescription device under 21 CFR Part 801.109 that is indicated prevention of external hemorrhoids during vaginal childbirth. FDA concludes that this device, and substantially equivalent devices of this generic type, 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, hemorrhoid prevention pressure wedge.

FDA identifies this generic type of device as:

> 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.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), 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 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 previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, with in 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 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 August 17, 2009, FDA filed your petition requesting classification of the Hem-Avert Perianal Stabilizer into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on August 5, 2010 automatically classifying the Hem-Avert Perianal Stabilizer in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. To classify the Hem-Avert Perianal Stabilizer into class I or 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 petition, FDA has determined that the Hem-Avert Perianal Stabilizer indicated for prevention of external hemorrhoids during vaginal childbirth 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.

Potential Risks

Identified Risk	**Recommended 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

In addition to the general controls of the act, the Hem-Avert Perianal Stabilizer is subject to the following special controls:

- The sale, distribution, and use of this device are restricted to prescription use in accordance with 801.109 of this chapter.

- The labeling should include specific instructions regarding the proper placement and use of the device.
- The device should be demonstrated to be biocompatible.
- Mechanical bench testing of material strength should demonstrate that the device will withstand forces encountered during use.
- Safety and effectiveness data should demonstrate that the device prevents hemorrhoids in women undergoing spontaneous vaginal delivery.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the 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 act. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the hemorrhoid prevention pressure wedge they intend to market prior to marketing the device and receive clearance to market from FDA.

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, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Glenn Bell, Ph.D. at (301) 796-6531.

Sincerely yours,

Jonette Foy, Ph.D.
Acting Deputy Director
for Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health