DE NOVO CLASSIFICATION REQUEST FOR
HEM-AVERT PERIANAL STABILIZER

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Hemorrhoid prevention pressure wedge**. 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.

NEW REGULATION NUMBER: 21 CFR 884.5200

CLASSIFICATION: II

PRODUCT CODE: OOA

BACKGROUND

DEVICE NAME: HEM-AVERT PERIANAL STABILIZER

SUBMISSION NUMBER: DEN090011

DATE OF DE NOVO: AUGUST 18, 2009

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REQUESTER'S RECOMMENDED CLASSIFICATION: II

INDICATIONS FOR USE

The Hem-Avert Perianal Stabilizer is indicated for the prevention of external hemorrhoids during vaginal childbirth.

LIMITATIONS

The Hem-Avert Perianal Stabilizer is a prescription device under 21 CFR Part 801.109.

The Hem-Avert Perianal Stabilizer should be removed immediately if the physician feels the instrument in any way interferes with the childbirth process.

Misuse or mishandling of the product may cause injury to the patient. Improper handling can

render the product unsuitable for its intended use. Other potential complications may include, but are not limited to:

- Infection - If the product sterility has been compromised.
- Pain, discomfort or abnormal sensation resulting from the presence of the instrument against the anus.
- Skin irritation.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

This is a single use, disposable, sterile instrument. The Hem-Avert™ Perianal Stabilizer consists of three components:

1. rigid polymer base manufactured from a medical grade polycarbonate
2. centrally located cushioning pad composed of a laminate of medical grade polyester non-woven tape and medical grade polyethylene foam tape
3. two lateral hook and loop adhesive strips (with liners) which provide the tension required to keep the instrument firmly in place during delivery.

The cushioning pad and adhesive strips are manufactured from materials commonly associated with medical instruments and used in medical procedures.

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

Material	Description	Contact
1	b(4) Hi Tack Conformable Double Coated Tape	Skin
2	b(4) Foam medical tape	Mucosal
3	b(4) Non-woven tape	Mucosal
4	b(4)	May come into contact with liquids that could leach material. Should be considered in mucosal contact.

Cytotoxicity (ISO Elution Method; ST-7221) - This study was based on the ISO 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: in vitro Methods guidelines. The test article was described as the Hem-Avert Perianal Stabilizer Device. An extract of the test articles was prepared using b(4)

b(4) Following incubation, the cultures were examined microscopically to evaluate cellular characteristics and percent cell lysis. The testing showed no signs of cytotoxicity.

Irritation (Intracutaneous Reactivity) - This study was based on the ISO 10993: Biological Evaluation of Medical Device, Part 10: Tests for Irritation and Sensitization. The test article was described as the Hem-Avert Perianal Stabilizer Device. b(4) Observations for erythema and edema were made at 24, 48 and 72 hours. The testing showed no evidence of significant irritation from the material tested in this study.

Sensitization (GPMT) - This study was based on ISO 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed Type Hypersensitivity. The test article was described as the Hem-Avert Perianal Stabilizer Device. b(4) Following a recovery period (14 days), test and control animals received a challenge patch of the appropriate test article extract or reagent control for 24h. Results of the study showed no signs of sensitization following use of saline or oil device extracts.

SHELF LIFE/STERILITY

The device is provided sterile by b(4) to achieve a sterility assurance level (SAL) of 10^{-6}. Sterilization validation was tested using 10 samples b(4) samples b(4) . Three samples had positive growth b(4) y and none had positive growth at b(4) . The bioburden was applied by direct transfer of b(4) b(4)) for at least 14 days. The device is packaged using Tyvek peel pouch.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

Electromagnetic and electrical concerns do not apply to this device.

MAGNETIC RESONANCE (MR) COMPATIBILITY

MR compatibility does not apply to this device as it is not intended to be used in an MR environment.

SOFTWARE

This device does not include software.

PERFORMANCE TESTING – BENCH

Static compression three-point bending testing was conducted on 5 samples of the Hem-Avert. The Hem-Avert was found to endure a compressive load of 188N (to flattening without breaking). The device is designed to withstand the pushing force exerted by a woman in labor without breaking. While bench testing cannot show that the device can stay in place during labor, .results from the clinical study demonstrated that the device stays in place during labor. See "Summary of Clinical Information" below.

SUMMARY OF CLINICAL INFORMATION

Primary Objective:

- Evaluate the safety and efficacy of the Hem-Avert as a method of preventing the occurrence of hemorrhoids during delivery

Sites:

- OBGYN physician clinics (n=4)
- Delivery sites (n=3)

Subjects:

- 176 subjects enrolled in study
- 101 subjects (61 control and 40 test subjects) completed study
- 86 subjects (52 control and 34 test subjects) in efficacy analysis (Note: subjects with pre-existing hemorrhoids were excluded)

Inclusion criteria:

- Subject is between 18 and 40 years of age, female and pregnant
- Subject is scheduled for vaginal delivery
- Subjects' pre-natal examination indicates that this is to be a single birth delivery

Exclusion criteria:

- Subject weighs less than 130 pounds at time of delivery
- Subject has hemorrhoids other than low grade
- Subject has had previous rectal surgery (e.g., hemorrhoidectomy)
- Subject has lacerations or anal fissures
- Subject has a documented allergy to the instrument's materials
- Subject's scheduled for vaginal delivery with anticipated complications (such as breech presentation)
- Subject is unable to understand and sign the informed consent form
- Subject is a prisoner

Note: One 17 year old patient and two patients with weights below 130 lbs. were included in the study, which are considereddeviations to inclusion criteria. These deviations were approved through deviation requests.

Continuation criteria:

- Dilation at 8-10 centimeters and there was no evidence of crowning prior to the initial visual examination.
- The presence of hemorrhoids (other than low grade) was not observed by the physician at the time of visual examination (ten centimeter dilation).
- The presence of lacerations or anal fissures was not observed by the physician at the time of visual examination.
- The subject was able to complete the vaginal birth process (did not deliver by Cesarean section)
- The subject did not receive an episiotomy as part of the delivery process
- The delivery did not result in multiple births
- The delivery did not result in a still birth
- The delivery did not involve complications such as failure to progress, shoulder dystocia or delivery requiring vacuum or forceps
- The subject's perineum is < 2 cm or instrument does not seat properly

Study Procedure:

- Screening visit – obtain medical history, sign informed consent
- Physical examination – at time of admission for delivery
- Placement of instrument – when dilated 8-10 cm
- Follow-up examination and data collection – prior to discharge from hospital

Table 1 below describes subject accounting within the study.

Table 1: Clinical Study Results

Summary	Treatment Group		All Subjects
	Hem-Avert	Control	
Screened			202
Randomized	87	89	176
Randomized with Existing External Hemorrhoids	10	7	17
Randomized with Prevention Possible	77	82	159
Excluded from Analysis	43	30	73
- C Section	11	19	30
- Episiotomy	4	6	10
- Perineum <2 cm	3	0	3
- Delivery Complications (Instrument Not Applied)	4	0	4
- Protocol Not Followed	1	0	1
- Subject Crowning	1	0	1

- Delivery at Non-study Hospital	5	1	6
- Delivered After Hours/Over Weekend/Investigator not Present	8	0	8
- Subject Withdrew Consent	1	0	1
- Subject Delivered Too Quickly	4	3	7
- Study Discontinued Before Delivery	1	1	2
Total Included in Efficacy Analysis	34	52	86

Results:

Table 2 describes subject demographics.

Table 2: Demographics

	Hem-Avert	Control	P-value
Number of Subjects	34	52	
Age (years)			
Mean (Std)	25.3 (4.53)	23.6 (4.55)	0.0712
Median	24.5	23.0	
Min, Max	18, 34	17, 35	
Weight (lbs)			
Mean (Std)	186.4 (33.91)	188.0 (37.62)	0.8841
Median	174.5	180.0	
Min, Max	129, 274	121, 276	
Previous Pregnancies			
Yes	25 (73.5%)	32 (61.5%)	0.3511
No	9 (26.5%)	20 (38.5%)	

Table 3 describes the device effectiveness results.

Table 3: Primary Endpoint Analysis

Summary	Hem-Avert®	Control	P-value
Efficacy Subjects	34	52	
Success	34 (100.0%)	39 (75.0%)	
Failure	0	13 (25.0%)	0.0012
Total	34	52	

The data from the clinical trial indicate that use of the Hem-Avert can aid in preventing the occurrence of hemorrhoids during vaginal delivery.

LABELING

The Hem-Avert Perianal Stabilizer complies with the labeling requirements under 21 CFR 807.87(e) and prescription device requirements under 21 CFR § 801.109. The device labeling bears the following: "Caution: Federal law restricts this device to sale by or on the order of a physician."

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of hemorrhoid prevention pressure wedge and the measures necessary to mitigate these risks.

Identified Risk	Mitigation Method
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

SPECIAL CONTROLS:

In combination with the general controls of the FD&C Act, the Hem-Avert Perianal Stabilizer is subject to the following special controls:

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 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.
5. Safety and effectiveness data should demonstrate that the device prevents hemorrhoids in women undergoing spontaneous vaginal delivery.

CONCLUSION

The de novo for the Hem-Avert Perianal Stabilizer is granted and the device is classified under the following:

Product Code: OOA
Device Type: Hemorrhoid prevention pressure wedge
Class: II
Regulation: 21 CFR 884.5200