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K072690

HEMAWAY LLC
RELIEF SOLUTIONS

510(k) Summary

Hemaway Seat

The following information is presented as required by 21 C.F.R. § 807.92:

Date: November 20, 2007

Section A: Administrative Information

DEC 07 2007

Submitter:
Hemaway LLC
2207 Concord Pike
PMB 528
Wilmington, Delaware 19803

Establishment Registration Number: To be obtained

Manufacturing Site:
Midbury Industries Inc.
86 East Merrick Road
Freeport, NY 11520
(516) 868-0600

Contact Person: Archie Rosenblum

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Section B: Device Identification

Device Name:	Hemaway Seat
Common Name:	Hemorrhoid Seat
Device Classification:	Unclassified
Panel:	Gastroenterology/Urology
Performance Standards:	None known established

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Section C: Device Description

The Hemaway Seat is an injection molded polypropylene copolymer plastic seat attached to a toilet seat that discretely locks into the contoured lid when not in use. The product is adjustable and is available in round and elongated versions. The product is assembled and attaches to the toilet in the same manner as a regular toilet seat. See illustrations below.

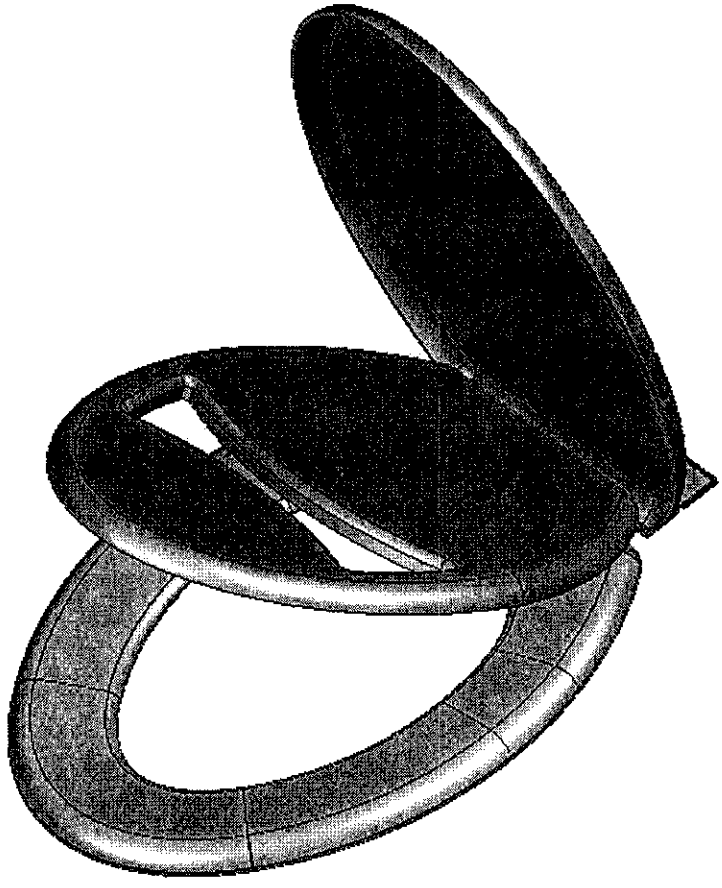

Figure 1

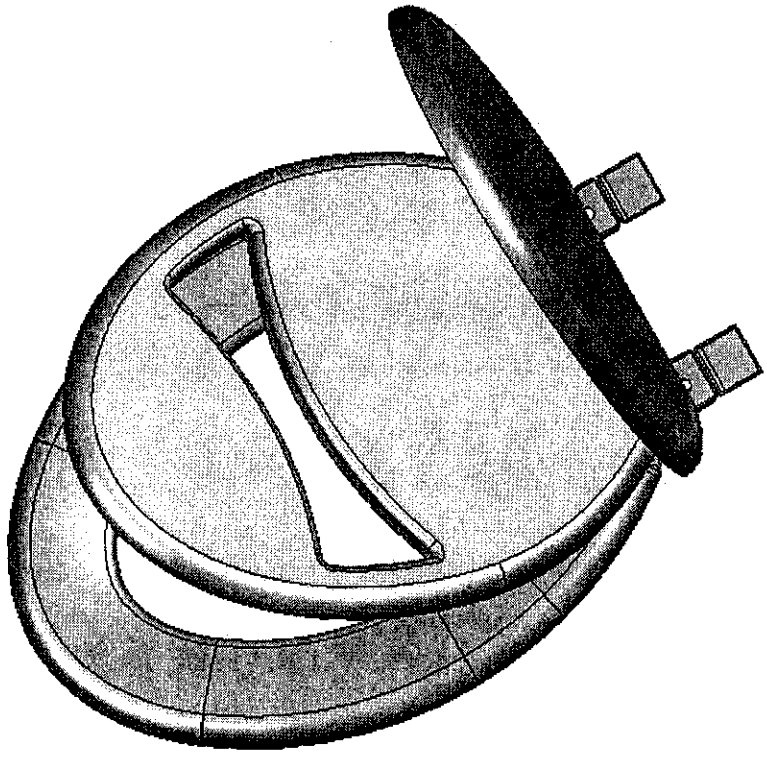

Figure 2

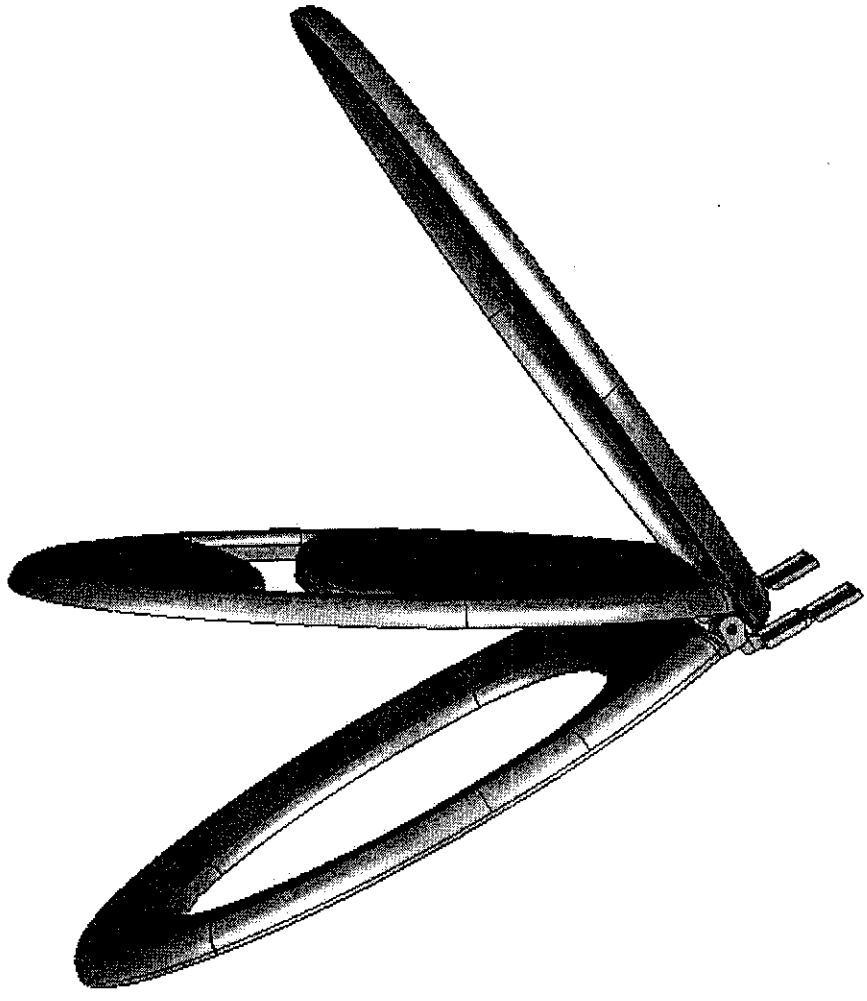

Figure 3

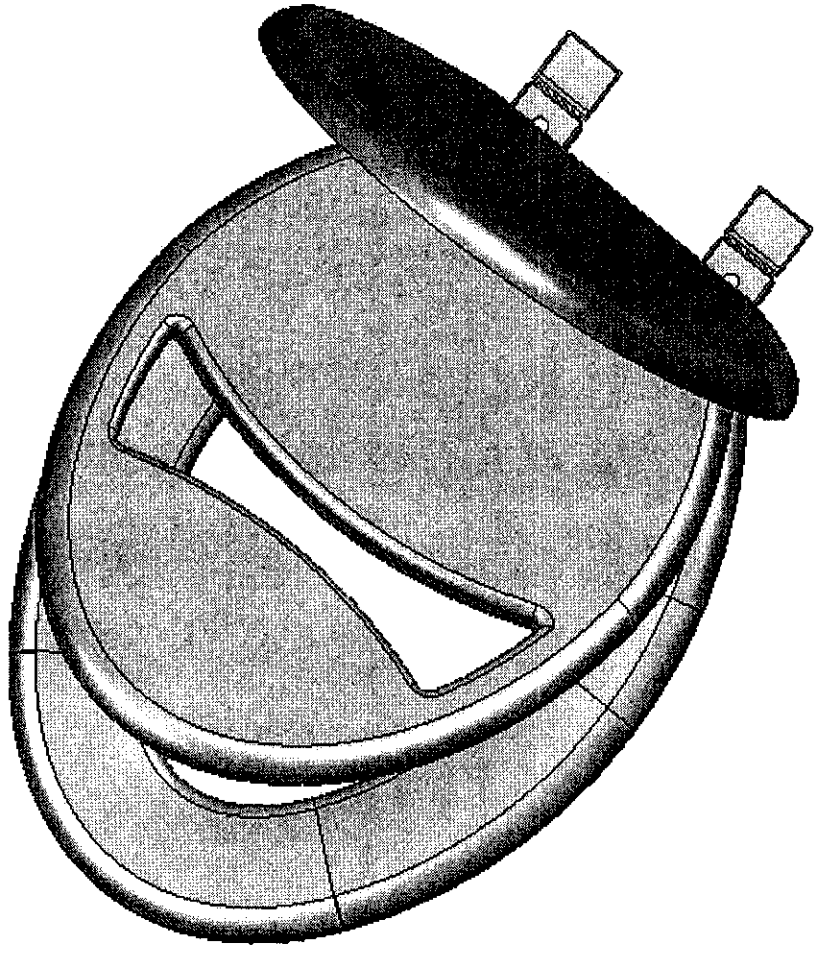

Figure 4

The user is instructed to sit on the seat facing forward in the same manner as sitting on a conventional toilet seat, positioned so that the hemorrhoids are in the center of the seat opening. This is intended to create a slight counter-pressure around the anal canal, which gently relieves the pain and pressure of the hemorrhoids.

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Indications for Use

510(k) Number (if known): K072690

Device Name: Hemaway Seat

Indications for Use: The Hemaway Seat is for the temporary relief from the pain and pressure of hemorrhoids. The device is for external use only.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Section D: Substantial Equivalence

Predicate Devices: Hemorest™ (K864470)
The Derby Raised Toilet Seat (K821860)

Narrative Description of Substantial Equivalence:

The Hemaway Seat is substantially equivalent to other FDA listed and 510(k) cleared hemorrhoid cushions. Specifically, the Hemaway Seat has the same intended use and similar physical characteristics as the Hemorest device. Although essentially the same in all significant respects, the Hemaway Seat is made of plastic while the Hemorest is made of foam, the Hemaway Seat attaches to a toilet while the Hemorest is portable, and the Hemaway Seat does not contain a crown feature but rather is available in two sizes.

The Hemaway Seat is also substantially equivalent to FDA listed and cleared raised toilet seats, such as the Derby Raised Toilet Seat, in material (polypropylene plastic), biocompatibility and method of use (*i.e.*, skin-to-product contact while seated). A comparison of the characteristics of the current device and the predicate devices is set forth in the chart below.

Comparison Chart:

Feature	**Hemaway**	**Hemorest**	**Derby**
Used in a sitting position	Yes	Yes	Yes
Provides temporary relief from the pressure and pain of hemorrhoids	Yes	Yes	No
Noninvasive	Yes	Yes	Yes
Contains a "crown" as a component of the device	No	Yes	No
Can be used in conjunction with other treatments	Yes	Yes	Yes
Made of polypropylene plastic	Yes	No	Yes
Integrated into toilet seat	Yes	No	Yes
Portable	No	Yes	No
Has direct contact with the body while sitting	Yes	No	Yes
Available in 2 sizes	Yes	No	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 07 2007

Mr. Archie Rosenblum
Hemaway LLC
2207 Concord Pike, Suite 528
PMB 528
WILMINGTON DE 19803

Re: K072690
Trade/Device Name: Hemaway Seat
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LRL
Dated: November 20, 2007
Received: November 21, 2007

Dear Mr. Rosenblum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072690

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072690