

510(k) Summary

K974645

P102

FEB 12 1998

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, INSIGHT Medical Corp. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." INSIGHT Medical chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

**Trade Name:** FemAssist™ Flexible

**Owner/Operator:** INSIGHT Medical Corporation  
580 Main Street  
Bolton, MA 01740  
Registration # 1221923

**Device Generic Name:** Urethral clamp

**Classification:** According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device is considered "unclassified." Urethral clamps are addressed in 21 CFR 876.5160. The FemAssist™ product code is 78MNG.

**Predicate Device:** FemAssist™  
Manufactured and Distributed by:  
INSIGHT Medical Corp.  
580 Main Street  
Bolton, MA 01740  
K963858

**Product Description:**

The INSIGHT Medical FemAssist™ device consists of a small, flexible, cylindrical, non-sterile device with a short profile which is manufactured from soft silicone material. The FemAssist™ fits over the external female urethral opening, between the labia, posterior to the clitoris and anterior to the vagina. The FemAssist™ is placed directly over the urethral opening where it is held in place by its own mild vacuum action, supporting and reinforcing the natural action of the muscles that control urine output and preventing accidental urine loss. Aquaphor ointment is applied to the device flange area prior to placing it over the urethral opening to help achieve a good seal. The flange area of the FemAssist™ Flexible device is thinner than that of the standard FemAssist™ cleared in K963858 for increased patient comfort.

**Indications for Use:**

The FemAssist™ Flexible is an external female continence device indicated for the management of urinary leakage in women suffering from stress urinary incontinence (SUI).

**Biocompatibility:**

The FemAssist™ Flexible device will be manufactured from materials identical to those used in the FemAssist™ standard device; therefore, no biocompatibility testing was performed in support of this submission.

**Safety and Performance:**

The following safety and performance tests were performed on the FemAssist™ Flexible:

1. Tensile test
2. Pull-off Test
3. Lift-off Pressure Test

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The results of this testing demonstrated that the physical characteristics of the modified FemAssist™ device are equivalent to those of the currently marketed FemAssist™.

**Clinical Testing:**

Market evaluation testing was performed at the Peakhurst community Health Centre, Peakhurst, New South Wales, Australia in early 1997. A total of 14 women evaluated the FemAssist™ Flexible device. Of these 14, 4 patients withdrew from the study. Five of the 14 achieved a quantitative improvement as measured by a reduction in urine leakage during 1-hour pad weight testing. Two additional women reported that they liked the FemAssist™ Flexible device even though they did not achieve a quantitative improvement in the pad weight testing. The remaining patient, a very active athlete, found the Flexible device to be more comfortable than the "standard" FemAssist™, but did not feel that her leakage was well controlled while sprinting and cycling with either device. She did report success with the FemAssist™ while jogging. Subjective, non-quantitative data was presented for the remaining two patients who reported that the FemAssist™ Flexible device was effective in controlling urine loss.

**Conclusion:**

Based on the indications for use, technological characteristics and performance testing, the INSIGHT Medical FemAssist™ Flexible has been shown to be safe and effective for its intended use.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

APR 26 2010

INSIGHT Medical  
Mr. Michael Vergano  
Director of Product Development/Operations  
580 Main Street  
BOLTON MA 01740

Re: K974645

Trade/Device Name: FemAssist™ Flexible Contenance Device  
Regulation Number: 21 CFR§ 876.5160  
Regulation Name: Urological clamp for males  
Regulatory Class: I  
Product Code: MNG  
Dated: December 10, 1997  
Received: December 12, 1997

Dear Mr. Michael Vergano:

This letter corrects our substantially equivalent letter of February 12, 1998.

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 (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 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.

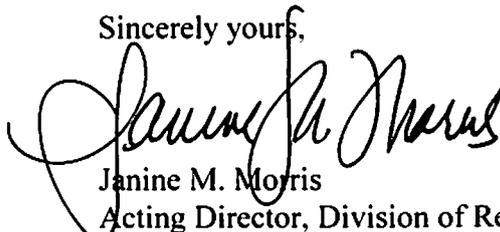
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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); 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K974645

Device Name: INSIGHT Medical FemAssist™ Flexible

Indications for Use:

The INSIGHT Medical FemAssist™ Flexible is an external female continence device indicated for the management of urinary leakage in women suffering from stress urinary incontinence (SUI).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Matting  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT  
and Radiological Devices  
510(k) Number K974645

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

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