

K963858
P174**INSIGHT Medical**580 Main St., Bolton, MA 01740
Phone 508-779-6848 FAX 508-779-6927

21 OCT 1997

510(k) Summary

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™ Urinary Incontinence Device

510(k) Premarket Notification: #K963858

Owner/Operator: INSIGHT Medical Corporation
580 Main St.
Bolton, MA 01740
Registration # 1221923
(INSIGHT Medical is a wholly owned subsidiary of Apple Medical Corp.)

Device Generic Name: Urethral Clamp

Classification: According to Section 513 of the Federal Food, Drug and Cosmetic Act, the device classification of a urethral clamp is Class I at 21 CFR 876.5160 (78FHA) by Gastro/Urology.
Also, Appliance, Incontinence, Urosheath Type are classified as Class I at 21 CFR 876.5250 (78EXJ) by Gastro/Urology.

Predicate Device: MINIGUARD (Currently called Impress)
By Advanced Surgical Intervention
Dana Point, CA (Now Uromed Corp., Needham, MA)

The Miniguard (Impress), similar to the FemAssist™, was cleared for marketing by the FDA on May 8, 1996 as a new stress urinary incontinence product. The product is a small triangular shaped disposable foam pad with a plastic substrate about the size of a quarter, with an adhesive coating on one side. When placed over the urethra, the pad forms a seal to help stop urine from leaking. To use, a woman places the adhesive side of the pad over the urinary opening, forming a seal.

Product Description: The FemAssist™ device is a small (3.5cm in diameter) cylindrical device with a short profile (2.0cm in height) designed and constructed (molded) to fit over the female urethra, between the labia, posterior to the clitoris and anterior to the vagina.

The FemAssist™ supports and reinforces the natural action of the muscles that control urine output and prevents accidental urine loss. The female urethra is located between the vagina and the clitoris, in the center of the area about 3cm in diameter. The FemAssist™ product is

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designed to be placed directly over the urethra where it will be held in place by it's own mild vacuum action.

Indications for Use:

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

Biocompatibility:

The following biocompatibility tests were performed on the FemAssist™ device:

1. NAmSA Microbial Limits Preparatory Test
 - Staphylococcus Aureus
 - Pseudomonas Aeruginosa
 - Escherichia Coli
 - Salmonella Typhimurium
2. NAmSA Microbial Limits - Screening
3. NAmSA Ames Salmonella/Mammalian Microsome Mutagenicity Assay for Mutagens
4. NAmSA USP Intracutaneous Toxicity Test in Rabbits
5. NAmSA Delayed Contact Sensitization Study
6. NAmSA Cytotoxicity Testing - By the USP Elution Method
7. NAmSA Pyrogen Test T10
8. NAmSA Hemolysis Test in Vitro
9. NAmSA Vaginal Mucosal Irritation Study in the rabbit (Saline Extract)
10. NAmSA Vaginal Mucosal Irritation Study in the rabbit (Cottonseed Oil Extract)
11. USP Muscle Implantation, Two rabbits (4 weeks) with Histopathology
12. USP Muscle Implantation, Three rabbits (9 weeks) with Histopathology
13. USP Muscle Implantation, Three rabbits (13 weeks) with Histopathology

Benchtop Safety and Performance Testing:

The following benchtop safety and performance tests were performed on the FemAssist™ device.

1. Tensile Test
2. Pull Test
3. Lift Off Pressure Test
4. Vacuum Test
5. Water Leakage Test

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Clinical Results: Safety & Efficacy:**FemAssist™ Clinical Study:**

A clinical study was conducted at three (3) US sites to determine if the FemAssist™ device could safely and effectively control urinary leakage in adult women suffering from various degrees of incontinence. The safety analysis was based on all women enrolled at the three clinical sites, however the effectiveness data was based on the data collected from one site.

Clinical Safety:

The study monitored all adverse events on 222 adult women who initially enrolled in the study. Of these patients 138 were followed for at least 30 days. Adverse events were obtained from voiding diaries and physician visits. The following adverse events were recorded during a combined trial involving 222 patients who used FemAssist™ for up to 30 days:

<u>Recorded Event</u>	<u># of Patients Recording Event</u>	<u>% of Total Patients in Trial</u>
Discomfort (patient reported)	78	35
Urinary Tract Infection	22	10
Urethral Irritation (abrasion, bruising, redness)	14	6
Bleeding	12	5
Discharge	6	3
Yeast Infection	2	1

Clinical Effectiveness:

The study used a one-hour standard pad weight test to measure device effectiveness. Each women was asked to wear a pre-weighed pad for one hour while performing light exercise. After one hour, the pad was removed and weighed again to determine the amount of urine leakage that had occurred during this period. Each women was then asked to use the device at home for 28 days, then return to the Doctor to repeat the one-hour pad test while wearing the FemAssist™ device. At one clinical site, data from 73 women was used to evaluate the effectiveness of the FemAssist™ device in women with SUI. (Women were included in this analysis if they leaked a minimum of 2.0g of urine during the standard one-hour pad weight test* or >15 g of urine during the 48 hour pad weight test**.) *Lose G., Versi E. Pad-weighing Tests in the Diagnosis and Quantification of Incontinence. Int Urogynecol 1 1992; 3:324-328 **Versi E., Orrego G., Hardy E., et al. Evaluation of the home pad test in the investigation of female urinary incontinence. British Journal of Obstetrics and Gynaecology 1996; 103: 162-167

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<u>% Reduction in Urine Loss</u>	<u># of Patients (%) n=73</u>
100% (no leakage)	24 (32.9%)
75-100%	22 (30.1%)
50-75%	10 (13.7%)
0-50%	6 (8.2%)
Increase in Urine Loss	11 (15.1%)

As the table indicates, 76.7% of the women achieved at least a 50% or greater reduction in urine loss. The women were also asked to keep a one-week voiding diary, recording the number of days the FemAssist™ device was worn and the number of dry days experienced while the device was worn. These data demonstrated that the women remained dry for approximately 65.9% of the recorded days.

Conclusion:

Based on the indications for use, performance testing, and clinical results, the INSIGHT Medical FemAssist™ device 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

Mr. Robert W. Schaefer
President
INSIGHT Medical Corporation
580 Main Street
BOLTON MA 01740

Re: K963858

Trade/Device Name: FemAssist™
Regulation Number: 21 CFR §876.5160
Regulation Name: Urological clamp for males
Regulatory Class: I
Product Code: MNG
Dated: October 13, 1997
Received: October 14, 1997

Dear Mr. Schaefer:

This letter corrects our substantially equivalent letter of original SE letter October 21, 1997.

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.

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

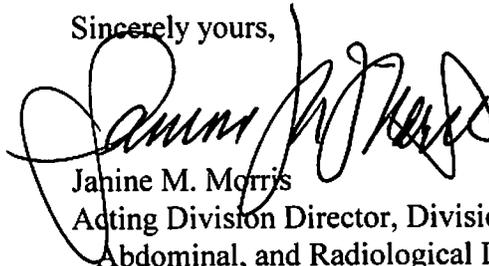
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and 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 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,



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

Enclosure

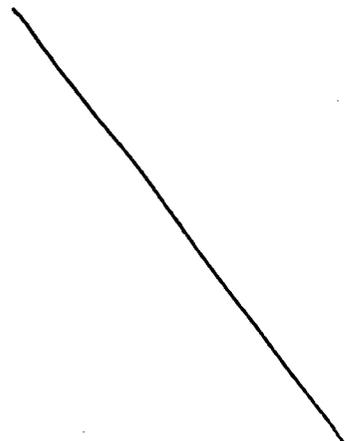
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510(k) Number (if known): K963858

Device Name: FemAssistTM Personal Urinary Control Device

Indications For Use:

The FemAssistTM 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. Sotby
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K963858

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-86)

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