

APR 30 2003

KOZ3905

Appendix V

510(k) Premarket Notification
Summary of Safety and Effectiveness Information

Athena Pelvic Muscle Trainer
April 15, 2003

1. Device Name
Trade Name: : Athena Pelvic Muscle Trainer
Common Names: : Athena Pelvic Muscle Trainer
Classification Name: Stimulator, Electrical, Non-Implantable, for Incontinence
2. Establishment Name & Registration Number:

Name: Athena Feminine Technologies

Number: none
3. Classification:
Title 21, Code of Federal Regulations,
§Sec. 876.5320 ProCode: KPI
4. Guidance Documents, Performance Standards and Special Controls:
At the present time, the following guidance documents are in effect for this device:

Guidance on the Content and Organization of a Premarket Notification.
5. Equivalent Device(s): Utah Medical, Liberty PFS-200 System (K960496), Pathway CTS 2000 (K001515)
Hollister, Microgyn n (K963222)
6. Applicant/Sponsor Name / Address:
Athena Feminine Technologies
179 Moraga Way
Orinda, CA 94563
(925) 254-6090
7. Company Contact: George Sarkis, CEO
Athena Feminine Technologies
179 Moraga Way
Orinda, CA 94563
(925) 254-6090
8. Submission Correspondent: Barbara Sarkis, CIO
Athena Feminine Technologies
179 Moraga Way
Orinda, CA 94563
(925) 254-6090

9. Description of the Device and Indications for Use:

Description of the Device: The Athena Pelvic Muscle Trainer is a vaginal two electrode stimulation probe operated through a FM remote control device. The probe is stored in an activator box that turns the probe on automatically when the probe is removed from the box.

Indications for use: The Athena Pelvic Muscle Trainer is intended to provide electrical stimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women.

K023905

	Athena Pelvic Muscle Trainer	Pathway CTS 2000 K001515¹	Liberty PFS-200 System K 960496	InCare Microgyn II K963222
Intended Use	Treatment of urinary incontinence	Treatment of urinary incontinence	Treatment of urinary incontinence	Treatment of urinary incontinence
Programmable Features	Intensity	Intensity, Session length	Channel, Intensity, Continuous-Intermittent	Intensity
Channel Switch	Yes	Yes	Yes	No
Intensity Adjustment	Yes	Yes	Yes	yes
Duty Cycle of Stimulation	2.5 sec stim / 2.5 sec rest	2 sec stim/1 sec rest	5 sec stim/ 10 rest	2 sec stim /4sec rest
Duration	15 minutes	0-30 minutes	30 minutes	15 minutes
Power Source	(Probe) 1 3.6 volt lithium battery (Remote) 3 AAA alkaline batteries	Unknown	(2) 3 volt lithium batteries	9V alkaline
Treatment Protocol	15 min/twice day	Set by physician	15 min/twice day	15 min/twice day
Mode of Operation	Intermittent	Intermittent	Intermittent/Continuous	Intermittent
Ingress Protection rating	IP67 – Protected from Dust and liquid ingress	Unknown	IPXO-no protection	Unknown
Output Current	0 – 70 mA	0-100 mA	0-65 mA	Unknown
Pulse Width	200 μ S	300 μ s	300 μ s	50-300 μ s
Output Type	Constant voltage over range of 100 to 1000 Ohms	Constant current over unknown range.	Constant current over range of 100 to 1000 Ohms	Unknown
Output Isolation between Electrodes	$>10^8$ Ohms	Unknown	$>10^8$ Ohms	$>10^{12}$
Number of Electrodes	2 stimulators	Unknown	2 stimulators	4 stimulators
Usage Conditions	Reusable-single patient use	Reusable-single patient use	Reusable-single patient use	Reusable-single patient use
Electrode Orientation	Circular	Circular	Circular	Circular
Probe Length	3.3 in. nominal	2.9 in nominal	2.8 in. nominal	4.5 in. nominal
Probe Diameter	.99 in. nominal	.70 in. nominal	.95 in. nominal	1 in. nominal
Electrode material	Stainless steel	Unknown	Stainless steel	Metal
Device Connection	RF Remote	Attached cord	Attached cord	Attached cord
Electrode Placement	Vaginal	Vaginal	Vaginal	Vaginal
Waveform Type	Square	Square	Square	Square
Waveform Shape	Asymmetrical	Asymmetrical	Symmetrical	Symmetrical
Frequency	12.5Hz/50 Hz	12.5/50/100/200	12.5Hz/50 Hz	10-400 Hz

The data for the Pathway CTS2000 Pelvic Floor Training System was obtained from their pre-market notification to include additional functionality. In this report a number of the specifications were not given and as a result they are not listed in the table.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2003

Ms. Barbara Sarkis
Chief Information Officer
Athena Feminine Technologies, Inc.
179 Moraga Way
ORINDA CA 94563

Re: K023905

Trade/Device Name: Athena Pelvic Muscle Trainer (PMT)
Regulation Number: 21 CFR §876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: 78 KPI
Dated: March 3, 2003
Received: March 4, 2003

Dear Ms. Sarkis:

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 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.

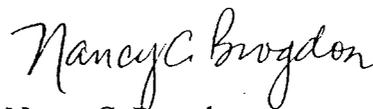
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



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

Enclosure

510(k) NUMBER: K023905

DEVICE NAME: *Athena Pelvic Muscle Trainer*

INDICATIONS FOR USE:

The **Athena Pelvic Muscle Trainer** is intended to provide electrical stimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional format 1-2-96)

David A. Reynolds
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023905