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10.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

David Mahoney  
Mahoney Enterprises  
200 North Main Street, South Building, Suite 6  
East Longmeadow, MA 01028  
Tel: 413.525.6313, Fax: 413.525.1999

This summary was prepared on September 30, 1999

2. The name of this device is the FemiScan™ Clinic System and the FemiScan™ Personal System. The common name is Biofeedback Monitoring device with vaginal EMG probe. Classification names are as follows:

Regulation Number	Classification Name
876.5320 78 KPI, II	Nonimplanted electrical continence device
884.1425 85 HIR, II	Perineometer

3. The FemiScan™ Clinic System is substantially equivalent to the following Hollister Incorporated predicate devices: InCare Pelvic Floor Therapy System with Desktop Computer PRS 9300 (K974048, K961872 and K930530) and the InCare Contimed Biofeedback devices for treatment of urinary incontinence (K960311 and K891774).
4. The FemiScan™ Clinic and Personal Systems consist of a palm-sized measuring unit with a computer-based user interface and data acquisition system for data collection and data transfer. The devices feature a 2 channel EMG vaginal probe.
5. Apart from electrical stimulation and male urinary incontinence applications, the FemiScan™ Clinic and Personal System has the same intended use as the legally marketed predicate device system. When used in the physician office, clinic or hospital environment, the FemiScan™ Clinic and Personal System is intended as an aid for exercising and training pelvic floor muscle activation and control. It is indicated in the treatment of stress and mixed female urinary incontinence under the supervision of a physician in the physician office, clinic, hospital environment or prescription home use.
6. The subject FemiScan™ Clinic and Personal System and the predicate Hollister devices both operate using the same

electromyography monitoring technology. However, the predicate devices use pressure EMG while the subject device uses electrical EMG. The measurement technology and the transmission of EMG signals are similar and therefore the technological characteristics are essentially the same as those of the legally marketed predicate devices.

7. The FemiScan™ Clinic and Personal System were subjected to safety and performance tests for compliance against applicable recognized standards. Additionally, verification, validation and testing activities were conducted to establish the performance and reliability characteristics of the FemiScan™ Clinic and Personal System. Testing involved system level tests, integration tests, data calculations, display results, FemiScan™ Personal System HomeTrainer™ communications, and safety testing from risk analysis. The FemiScan™ Personal System was evaluated for suitability as a prescription home use device in a user study conducted under the direction of Kuopio University Hospital. No adverse events occurred during the study.



JAN 10 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Mega Electronics Ltd.  
c/o Mr. David Mahoney  
Mahoney Enterprises  
200 North Main Street  
South Building, Suite 6  
East Longmeadow, MA 01028Re: K993411  
Mega Electronics Femiscan™ Clinic System and  
Femiscan™ Personal System  
Dated: October 5, 1999  
Received: October 12, 1999  
Regulatory Class: II  
21 CFR 884.1425/Procode: 85 HIR  
21 CFR 876.5320/Procode: 78 KPI

Dear Mr. Mahoney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number  
(if known)

K 993411

Device Name

The Mega Electronics Ltd., FemiScan™ Clinic System and FemiScan™ Personal System

Indications for Use

Indications: The FemiScan™ devices are intended as an aid for exercising and training pelvic floor muscle activation, control and optionally coordination with the abdominal muscle group. It is indicated in the treatment of stress and mixed female urinary incontinence under the supervision of a physician. The FemiScan™ Clinic System is used in the physician office, clinic, or hospital environment. The FemiScan™ Personal System is used to supplement these exercises in the home environment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use

  
**(Division Sign-Off)**  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K993411