

JUN 30 1997

K971527
Empi® 142

Cost Effective Health Care Solutions

SUMMARY OF SAFETY AND EFFECTIVENESS
InnoSense Pelvic Floor Stimulation and Electromyography System

Date of Summary June 17, 1997

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Empi, Inc.
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A. General Provisions

Submitter's Name: Empi, Inc.

Submitter's Address: 599 Cardigan Road
St. Paul, Minnesota 55126-3965

Contact Person: Carolyn M. Steele Husten
Regulatory Affairs Manager

Proprietary Name: InnoSense Pelvic Floor Stimulation and
Electromyography System

Common Name: Pelvic Floor Stimulation and Biofeedback Device

Classification Name: Non-Implanted Electrical Continence Device
Biofeedback Device

B. Name of Predicate Devices

- ◆ Verimed Myoexerciser III, K892649
- ◆ Thought Technology InControl, K935213
- ◆ Verimed Veristim, K893220
- ◆ Innova Pelvic Floor Stimulation System, K941911
- ◆ Minnova Pelvic Floor Stimulation System, K970307

C. Device Description

List of Components

The InnoSense Pelvic Floor Stimulation and Electromyography (EMG) System is comprised of a external stimulator/electromyography reader, leadwires (for surface EMG only) and electrodes. The device has a one channel stimulation function and a two channel EMG function. It is battery powered by two 1.5 volt (AA) batteries, with a low battery indication shown on the LCD Panel. The electrodes used to stimulate the pelvic floor muscles consist of either a vaginal or rectal electrode. The EMG function uses two electrodes consisting at the most one Vaginal or Rectal electrode and/or one or two surface EMG electrodes. One electrode is used to sense pelvic floor muscle activity and one is to sense accessory muscle activity such as the abdominal or gluteal muscles.

Electrical Characterization

External Stimulator

The external stimulator function provides stimulus output to the electrode and can be adjusted to deliver stimulation at an peak pulse intensity range of 0 to 100mA.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Carolyn M. Steele Husten
Regulatory Affairs Manager
Empi, Inc.
599 Cardigan Road
St. Paul, Minnesota 55126-3965

Re: K971527
InnoSense Pelvic Floor Stimulation and
Electromyography System
Dated: April 25, 1997
Received: April 28, 1997
Regulatory class: II
21 CFR §876.5320/Product code: 78 KPI
21 CFR §884.1425/Product code: 85 HIR

Dear Ms. Husten:

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 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 requirement, 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/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: (if known): K971527

Device Name: InnoSense Pelvic Floor Stimulation and Electromyography System

Indications for Use:

The InnoSense System is indicated for acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Improvement of urethral sphincter closure, Strengthening of pelvic floor muscles, Inhibition of the detruser muscle through reflexive mechanisms. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Sathiy
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971527

Prescription Use (Per 21 CFR 801.109)

OR Over-The Counter Use