K983206

Empi®

Cost Effective Health Care Solutions

NOV 3 1998

SUMMARY OF SAFETY AND EFFECTIVENESS
Innova Small Vaginal and Rectal Stimulation Electrode

Date of Summary: September 11, 1998

Empi, Inc.
599 Cardigan Road
St. Paul, Minnesota
55126-4099 USA

612-415-9000
FAX 612-415-7305

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
Classification Name:	Non-Implanted Electrical Continence Device 21 CFR Part 876.5320
Proprietary Name:	Innova® Small Vaginal and Rectal Stimulation Electrode
Common Name:	Pelvic Floor Stimulation Device

B. Name of Predicate Devices

- Empi, Inc. Innova Rectal or Small Vaginal EMG Sensing Electrode K952688
- Empi, Inc. Innova Rectal Stimulation Electrode K954272
- Innova® ComfortPulse™ Vaginal Electrodes (Small and Std.) K964577
- Innova® Vaginal Electrode K940091

C. Device Description

The Small Vaginal and Rectal Stimulation Electrode is identical in design to the predicate rectal electrode device except for the addition of vaginal use for stimulation. There were no design changes required or made to allow for this change.

D. Intended Use

The electrode is indicated for pelvic floor stimulation use in the treatment of urinary incontinence and monitors and allows assessment of EMG activity of the pelvic floor muscles. The electrode can be used either vaginally and rectally; it should not be interchanged between the two positions. The electrode is reusable between patients if reuse instructions are followed.

E. Non-Clinical and Clinical Test Summary

A Clinical study was performed to establish equivalence between this electrode used vaginally and the currently marketed stimulation electrodes. This study confirmed the suitability of performance of this electrode.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 1998

Ms. Carolyn M. Steele Husten
Regulatory Affairs Manager
Empi, Incorporated
599 Cardigan Road
St. Paul, Minnesota 55126-4099

Re: K983206
Empi Small Vaginal and Rectal Stimulation Electrode
Dated: September 11, 1998
Received: September 14, 1998
Regulatory Class: II
21 CFR §876.5320/Product Code: 78 KPI

Dear Ms. Steele Husten:

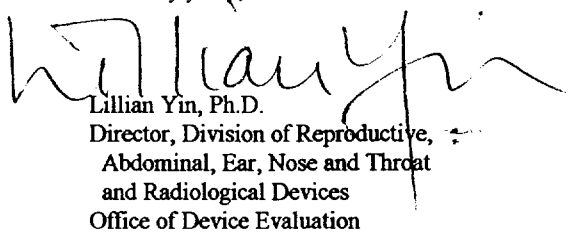
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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,



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): Unknown at time of submission
Device Name: Small Vaginal and Rectal Electrode
Indications for Use:

The electrode is indicated for pelvic floor stimulation use in the treatment of urinary incontinence and monitors and allows assessment of EMG activity of the pelvic floor muscles. The electrode can be used either vaginally and rectally; it should not be interchanged between the two positions. The electrode is reusable between patients if reuse instructions are followed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983206

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)