

**SUMMARY OF SAFETY AND EFFECTIVENESS**

AUG 14 1997

**Reusable Vaginal and Rectal Electrodes**

Date of Summary May 30, 1997

Page 1 of 1

**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® ComfortPulse Vaginal Electrodes (Small  
 and Standard)  
 Innova® Rectal Electrode  
Common Name: Pelvic Floor Stimulation Device

**B. Name of Predicate Devices**

- Empi, Inc. Minnova Pelvic Floor Stimulation System K970307
- Empi, Inc. ComfortPulse Regular and Small Electrode K964577
- Empi, Inc. Innova Rectal or Small Vaginal EMG Sensing  
 Electrode K952688
- Empi, Inc. Innova Rectal Stimulation Electrode K954272

**C. Device Description**

The Reusable Vaginal and Rectal Electrodes are identical to the predicate devices except for the addition of "multi-patient use" and reuse instructions. There were no design changes required or made to allow for this change.

**D. Intended Use****Indication for Use - Stimulation:**

The electrode is indicated for use in the treatment of urinary incontinence. The electrode is reusable if reuse instructions are followed.

**Indication for Use - Sensing:**

The electrode monitors and allows assessment of the EMG activity of the pelvic floor muscles. The electrode is reusable if reuse instructions are followed.

**E. Non-Clinical and Clinical Test Summary**

Non-clinical tests were performed to validate the sterilization process and instructions.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 14 1997

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

Re: K972054  
Innova® ComfortPulse Vaginal Electrodes  
(Small and Standard)  
Innova® Rectal Electrode  
Dated: May 30, 1997  
Received: June 2, 1997  
Regulatory Class: II  
21 CFR §876.5320/Product Code: 78 KPI

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

K972054 --

510(k) Number: (if known): Unknown at time of submission

Device Name: Reusable Vaginal and Rectal Electrodes

Indications for Use:

Indication for Use - Stimulation:

The electrode is indicated for use in the treatment of urinary incontinence. The electrode is reusable if reuse instructions are followed.

Indication for Use - Sensing:

The electrode monitors and allows assessment of the EMG activity of the pelvic floor muscles. The electrode is reusable if reuse instructions are followed.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K972054

Prescription Use   *e*   OR Over-The Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)