APR 22 1997

Empi®

Cost Effective Health Care Solutions

SUMMARY OF SAFETY AND EFFECTIVENESS

Minnova Pelvic Floor Stimulation System

Date of Summary January 24, 1997

K970307

Empi, Inc.
599 Cardigan Road
St. Paul, Minnesota
55126-3965 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:	Minnova Pelvic Floor Stimulation System
Common Name:	Pelvic Floor Stimulation Device

B. Name of Predicate Devices

- Empi, Inc. Innova Pelvic Floor Stimulation System, K9411911/B
- Hollister Mycrogym II Stimulation Device, K891773
- Utah Medical Liberty System, K960496

C. Device Description

List of Components

The Minnova Pelvic Floor Stimulation System is comprised of a external stimulator and an electrode. The device when used with the Innova® ComfortPulse® Vaginal electrodes (ComfortPulse Electrodes) (K964577 - currently under review at the FDA), Innova Vaginal Electrode (K910081), and Innova® Rectal Stimulation Electrode (Innova Rectal Electrode) (K954272), stimulates the muscles of the pelvic floor to achieve and maintain urinary continence. The electrodes are identical to those previously submitted except for the addition of touchproof connectors to comply with *"Medical Devices; Performance Standards for Electrode Lead Wires and Banning of Unprotected Electrode Lead Wires; Proposed Rule."* There is no adapter required to connect the electrodes to the device. The components of the system are placed in a soft-sided carrying case.

Electrical Characterization

External Stimulator

The Minnova is a battery powered electrical stimulator which provides stimulus output to the electrode and can be adjusted to deliver intermittent or continuous stimulation at an peak pulse intensity range of 0 to 100mA. The ramp up/down time is 2 seconds. The stimulator is capable of providing electrical impulses at frequencies of either 12.5Hz or 50 Hz. The pulse width is 300μs. The work to rest ratio (duty cycle) is 5:10 (5 seconds on/10 seconds off). The ComfortPulse Electrodes and Innova Rectal Electrode are fully compatible with the stimulator with the touchproof connector. The device is not programmable by the patient or the clinician and there are not any biofeedback components.

D. Intended Use

The Minnova Pelvic Floor Stimulation System is indicated for acute and ongoing treatment of urinary incontinence in cases where the following results may improve urinary control: Improvement of urethral sphincter closure, Strengthening of pelvic floor muscles, Inhibition of the detruser muscle through reflective mechanisms.

E. Non-Clinical and Clinical Test Summary

Non-clinical tests were performed to establish that the device when used with the ComfortPulse, Innova Vaginal and Innova Rectal electrodes meet specifications, thus providing evidence that the device when used with the electrodes are substantially equivalent to predicate devices and do not introduce new safety or effectiveness issues. Non-Clinical Tests consisted of verification of the specifications listed in the Table of Similarities and Differences, software verification and validation testing described in Section II, Part D, EMI Testing described in Section II, Part B and an FMECA test.