K042057

DEC 17 2004

510(k) Summary
for
Infinity Electrotherapy System

1. SPONSOR

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

Contact Person: Kathleen Schmitt
Telephone: (651) 415-9000

Date Prepared: December 13, 2004

2. DEVICE NAME

Proprietary Name:	Infinity Electrotherapy System
Common/Usual Name:	Electrical Muscle and Nerve Stimulator
Classification Names:	Powered Muscle Stimulator, Interferential Current Stimulator

3. PREDICATE DEVICES

Empi 300 PV	K021100
Ryan Telemedicine	K030254

4. INTENDED USE

The Infinity is a multi-function electrotherapy device with various treatment modes that allow for conventional interferential and premodulated interferential current stimulation (IFS) and is indicated for the following conditions:

- Symptomatic relief of acute pain
- Symptomatic relief and management of chronic intractable pain
- Symptomatic treatment for post-surgical and post-trauma acute pain

5. DEVICE DESCRIPTION

The Infinity is a multifunction electrotherapy device with various treatment modes that allows for interferential current stimulation (IFS) and premodulated interferential current stimulation. It has the ability to provide two channels of conventional interferential and premodulated interferential stimulation. The Infinity offers the following features:

- Channels 1 and 2, which are multi-purpose outputs (IF and PM IF)
- Each channel has a dedicated intensity control
- Maximum stimulation of 50 mA/500 V from each channel
- Timed therapy sessions
- Continuous stimulation
- Adjustable pulse rates
- Balanced asymmetrical and symmetrical biphasic waveforms
- Seven programs: three for conventional interferential, three for premodulated interferential and one for custom stimulation
- Lock option for clinician to control treatment regimens and stimulus intensity
- Pause function for patient to pause stimulation. During pause, the timer will not count down if timing has been set up. Upon restart, the device assumes the previous treatment stimulation parameters but a stimulus intensity of zero

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Infinity is an extension of the 300 PV and is similar in design and functions. Both offer multiple treatment programs, and the user can either choose one or more of these options or customize the treatment regimen within the available parameter ranges. The Infinity is a two-channel system that includes conventional and premodulated interferential stimulation whereas the 300 PV is a four-channel system. Additionally, it is not indicated for NMES, for FES or TENS since it does not include the accessories for FES, nor does it include the waveforms for FES and TENS. The conclusion of this technical comparison is that the Empi Infinity is substantially equivalent to the predicate devices for the indications specified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Empi, Inc.
C/o Ms. Mary McNamara-Cullinane, RAC
Medical Device Consultants, Inc.
Staff Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K042057
Trade/Device Name: Infinity Electrotherapy System
Device Name: Interferential current therapy
Regulatory Class: Unclassified
Product Code: LIH
Dated: December 8, 2004
Received: December 9, 2004

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

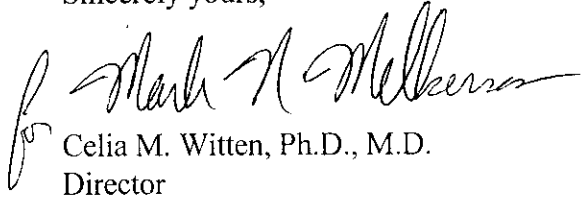
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: *Infinity Electrotherapy System*

Indications for Use:

The Infinity is a multi-function electrotherapy device with various treatment modes that allow for conventional interferential and premodulated interferential current stimulation (IFS) and is indicated for the following conditions:

- Symptomatic relief of acute pain
- Symptomatic relief and management of chronic intractable pain
- Symptomatic relief for post-surgical and post-traumatic acute pain

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042057