JUN 1 8 2002

K021100

1 of 3

510(k) Summary
for
300 PV Complete Electrotherapy System

1. SPONSOR

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

Contact Person: John Buan
Telephone: (651) 415-9000

Date Prepared: April 2, 2002

2. DEVICE NAME

Proprietary Name:	300 PV Complete Electrotherapy System
Common/Usual Name:	Electrical Muscle and Nerve Stimulator
Classification Names:	Powered Muscle Stimulator, Transcutaneous Nerve Stimulator, Interferential Current Stimulator, External Neuromuscular Functional Stimulator

3. PREDICATE DEVICES

Empi Focus – K951951
JACE Tristim – K931871
RS Medical RS-4M+ - K000114

4. INTENDED USE

The 300 PV is a multifunction electrotherapy device with various treatment modes that allow for neuromuscular electrical stimulation (NMES), transcutaneous electrical nerve stimulation (TENS), interferential current stimulation (IFS) and functional electrical stimulation (FES).

As a NMES device, the 300 PV is indicated for the following conditions:

- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion
- Re-educating muscles
- Relaxation of muscle spasm
- Increasing local blood circulation
- Prevention of venous thrombosis of the calf muscles immediately after surgery

As a TENS device, the 300 PV is indicated for the following conditions:

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

As an IFS device, the 300 PV is indicated for the following conditions:

- Symptomatic relief of acute pain
- Symptomatic relief and management of chronic pain

As a FES device, the 300 PV is indicated for the following condition:

- Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.

5. DEVICE DESCRIPTION

The Empi 300 PV Complete Electrotherapy System (300 PV) is a battery-powered, multifunction device intended to provide clinicians with the flexibility to prescribe multiple stimulation therapy regimens with the same device. The 300 PV offers the following features:

- Two independent stimulation channels (CH1 and CH2), each of which can provide NMES, TENS, IF, or FES therapy. HV therapy can be accomplished using CH1.
- Two independent intensity controls corresponding to each of the stimulation channels with a maximum stimulation of 100 mA from each channel.
- Timed therapy sessions

- Continuous or cycled stimulation
- Adjustable pulse rates
- Adjustable ON and OFF time controls
- Balanced asymmetrical and symmetrical biphasic waveforms
- Thirteen preprogrammed regimens: five for NMES; one for TENS; one for IF; two for HV and four that can be customized by the clinician (two NMES and two HV).
- Lock option for clinician to control treatment regimens and stimulus intensity
- Pause button for patient to pause stimulation. During pause, the timer will not countdown if timing has been set up. Upon restart, the device assumes the previous treatment stimulation parameters but a stimulus intensity of zero.
- Optional external hand or foot switch used to control the device output during when used as an FES device for gait training

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The 300 PV is an extension of the Empi Focus and is similar in design and functions. Both offer preprogrammed treatment regimens, and the user can either choose one or more of these options or customize the treatment regimen within the available parameter ranges. The 300 PV incorporates several improvements over the Focus, including a simplified user interface for the preprogrammed regimens and the addition of the interferential and high voltage regimens. However, high voltage galvanic stimulation is available on the JACE Tristim and interferential current stimulation is available on the RS Medical RS-4M+.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2002

Empi
C/O Sheila Hameon-Heyer, Esq., RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K021100
Trade/Device Name: 300 PV Complete Electrotherapy System
Regulation Number: 21 CFR 890.5850, 21 CFR 882.5810, 21 CFR 882.5890 and unclassified
Regulation Name: Powered Electrical Muscle Stimulator, Functional Neuromuscular Electrical Stimulator, Transcutaneous Electrical Nerve Stimulator, and Interferential Current Electrical Stimulator
Regulatory Class: Class II
Product Code: IPF, GZI, GZJ and LIH
Dated: April 2, 2002
Received: April 4, 2002

Dear Ms. Hameon-Heyer:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Melkerson

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

510(k) Number (if known): _____

Device Name: *300 PV COMPLETE ELECTROTHERAPY SYSTEM*

Indications for Use:

The 300 PV is a multifunction electrotherapy device with various treatment modes that allow for neuromuscular electrical stimulation (NMES), transcutaneous electrical nerve stimulation (TENS), interferential current stimulation (IFS), and functional electrical stimulation (FES).

As a NMES device, the 300 PV is indicated for the following conditions:

- Retarding or preventing disuse atrophy
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K021100

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

(Optional Format 1-2-96)