K032928

DEC 1 9 2003

510(k) Summary
MediPhysics Pain Treatment System, Model 1

1. SPONSOR

MediPhysics Pain Centers of America
13 Orchard Road, Unit 108
Lake Forest, California 92630

Contact Person: James Rogers
Telephone: (949) 215-0145, extension 10

Date Prepared: November 24, 2003

2. DEVICE NAME

Proprietary Name:	MediPhysics Pain Treatment System, Model 1
Common/Usual Name:	Electro-Magnetic Device for the Treatment of Pain
Classification Name:	Class II; 21CFR 882.5890; Product Code GZJ

3. PREDICATE DEVICES

- Therapeutic Devices Inc. TENS (K894127)
- Empi Epix VT TENS (K970203)
- Electro-Acuscope 85 (K883911)
- Medical Devices Matrix 1 TENS model 4700s (K895473)
- Well Life Health Care Mini TENS WL-2403 (K020020)
- CEFAR Primo (K020803)

4. DEVICE DESCRIPTION

The MediPhysics Pain Treatment System, Model 1, consists of a control console, two Treatment Probes (electrodes), and a Security Cartridge. The system operates on 115V wall current. Treatment, intended to take place under the supervision of a physician in a medical setting, consists of applying very low current to painful tissue and associated trigger points with the Treatment Probes.

5. INTENDED USE

The MediPhysics Pain Treatment System, Model 1, is intended for temporary symptomatic relief of chronic intractable pain, and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

MediPhysics has determined that the MediPhysics Pain Treatment System, Model 1, is substantially equivalent to the cited predicate devices based on intended use, indications for use, design characteristics, and technological characteristics and that the differences between the MediPhysics Pain Treatment System, Model 1, and cited predicate devices are minor and raise no new issues of safety or effectiveness.

7. PERFORMANCE TESTING

The MediPhysics Pain Treatment System, Model 1, has been systematically tested and test results demonstrate that it fulfills design and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2003

Mr. Morten Simon Christensen
Representing MediPhysics Pain Centers of America
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050-4169

Re: K032928
Device Name: MediPhysics Pain Treatment System, Model 1
Regulation Number: 21 CFR 882.5890
Regulation Names: TENS Device for Pain Relief
Regulatory Class: Class 2
Product Codes: GZJ
Dated: December 2, 2003
Received: December 4, 2003

Dear Mr. Christensen:

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 (301) 594-4648. 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,

for Mark N Milkens

Celia M. Witten, M.D., Ph.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): K032928

Device Name: MediPhysics Pain Treatment System, Model 1

Indications for Use: The MediPhysics Pain Treatment System, Model 1, is intended for temporary symptomatic relief of chronic intractable pain, and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

PRESCRIPTION USE X

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

Division of General, Restorative
and Neurological Devices

K032928

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

(Optional Format 1-2-96)