K070474

510(k) Summary
NewLife Sciences TMR

APR 25 2007

1. SPONSOR

NewLife Sciences LLC
51 Pondview Dr
Merrimack, NH 03054

Contact Person: Ronald Weinstock
Telephone: (603) 429-3022

Date Prepared: December 11, 2006

2. DEVICE NAME

Proprietary Name:	NewLife Sciences LLC, Model TMR
Common/Usual Name:	Transcutaneous Electrical Nerve Stimulator (TENS) for pain relief.
Classification Name:	Class II; 21 CFR 882.5890; Product Code GZJ

3. PREDICATE DEVICES

MediPhysics Pain Centers of America (K032928)
Empi Epix VT TENS (K970203)
Therapeutic Devices Inc. TENS (K894127)
Medical Devices Matrix 1 TENS model 4700s (K895473)
Well Life Health Care Mini TENS WL-2403 (K020020)
CERFAR Primo (K020803)
Electro-Acuscope 85 (K883911)

4. DEVICE DESCRIPTION

The NewLife Sciences LLC, Model TMR, 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 NewLife Sciences LLC, Model TMR, 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

NewLife Sciences LLC, Model TMR is identical to the MediPhysics Pain Centers of America (K032928) which has been determined to be 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 NewLife Sciences TMR and cited predicate devices are minor and raise no new issues of safety or effectiveness.

7. PERFORMANCE TESTING

The NewLife Sciences TMR 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

NewLife Sciences, LLC
C/O Danial W. Lehtonen
Staff Engineer
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
Twinsburg, Ohio 44087

APR 25 2007

Re: K070474
Trade/Device Name: Model TMR
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator (TENS) for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: March 29, 2007
Received: March 30, 2007

Dear Mr. Lehtonen:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
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: NewLife Sciences LLC, Model TMR

Indications For Use: The NewLife Sciences LLC, Model TMR, 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____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070474