K083494

510(k) Summary of Safety and Effectiveness
(As described in 21 CFR 807.92)

JAN - 6 2009

Date Prepared: **9-1-08**

Trade Name/Device: **Ultima Five™**

Applicant Information:

Pain Management Technologies, Inc.
1340 Home Ave. Bldg. A
Akron, OH 44310
800-239-7880 (phone)
888-304-5454 (fax)
Contact: Joshua Lefkovitz

Registration No. 1528161

Device Generic Name: TENS (Transcutaneous Electrical Nerve Stimulator)

Classification:

Class II (21CFR 882.1320)
Classification Name: Transcutaneous electrical nerve stimulator for pain relief
Product Code: GZJ
Regulation number 21 CFR 882.5890

Predicate Devices: The Easy Med TN-28C, TN-28C- K040253

Device Description: The Ultima Five consists of electrodes, the lead wires, and the signal generator. The Stimulator is portable, battery operated and rechargeable. The Lead wires connect the electrodes to the stimulator. These electrodes complete an electrical circuit allowing current to flow. The stimulator produces a pulsed electrical signal through the lead wires and electrodes at the treatment site.

Statement of intended use: The Ultima Five is indicated for use as an adjuctive therapy in reducing the level of chronic, acute, and post surgical pain.

Summary of technology of the Utima Five vrs. the predicate EasyMed device:
The Ultima Five and the Easymed TN28c generate the exact same electrical output. They produce the same frequency. The same wave form and similar modes. The same voltage output range, as well as the same dual channel output performance. Pulse widths and max output values are identical as well. The Ultima Five utilizes an LCD screen to display the settings

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Pain Management Technologies, Inc.
% Mr. Josh Lefkovitz
1340 Home Avenue, Building A
Akron, Ohio 44310

Re: K083494
Trade/Device Name: Ultima Five™
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: II
Product Code: GZJ
Dated: October 21, 2008
Received: November 25, 2008

Dear Mr Lefkovitz:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Mark N. Melkerson

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 Statement

510k Number: N/A

Device Name: Ultima Five™

Indication for Use:

The Ultima Five™ external, non-invasive, non-narcotic, electrotherapy device is indicated for use as an adjunctive therapy in providing symptomatic pain relief for chronic, acute, or post-operative pain.

These devices are to be used or sold only under the direct supervision or order of a licensed practitioner. A prescription is required to obtain this product.

Prescription Use ___√___ (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 OF NEEDED)

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

510(k) Number k083494