K081255

510(k) Summary
for the Competitive Technologies, Inc.
Scrambler Therapy MC-5A TENS Device
(per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

FEB 20 2009

Competitive Technologies, Inc.
777 Commerce Drive
Fairfield, CT 06825

Contact Person: Aris Despo
Telephone: 203-368-6044

Date Prepared: May 1, 2008

2. DEVICE NAME

Proprietary Name:	Scrambler Therapy MC-5A TENS Device
Common/Usual Name:	Electrical Nerve Stimulator
Classification Names:	Transcutaneous Electrical Nerve Stimulator

3. PREDICATE DEVICES

- Ito ES-160, K051020
- Neuro Wave 6, K062003

4. DEVICE DESCRIPTION

The Scrambler Therapy MC-5A TENS Device is a multi-channel TENS device which allows simultaneous treatment of a number of pain sites. Stimulation impulses are generated and controlled according to a stored program to provide pain relief.

5. INTENDED USE

The Scrambler Therapy MC-5A TENS Device is indicated for:

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

- Symptomatic relief of acute pain
- Symptomatic relief of post-operative pain

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Competitive Technologies, Inc. claims substantial equivalence of the Scrambler Therapy MC-5A TENS Device to the predicate devices based on the intended use, fundamental technology, and operation characteristics. A side-by-side comparison of the Scrambler Therapy MC-5A TENS Device and the cited predicate devices is included in the 510(k).

7. PERFORMANCE TESTING

Testing of the Scrambler Therapy MC-5A TENS Device demonstrates that the device meets design and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Competetive Technologies, Inc.
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Cullinane, RAC
Senior Regulatory Affairs Specialist
49 Plain Street
North Attleboro, Massachusetts 02760

FEB 20 2009

Re: K081255
Trade/Device Name: Competitive Technologies, Inc. Scrambler Therapy MC-5A TENS Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: February 6, 2009
Received: February 9, 2009

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 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 Biometric's (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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K081255

Device Name: Competitive Technologies, Inc. Scrambler Therapy MC-5A TENS Device.

Indications for Use:

The Scrambler Therapy MC-5A TENS Device is indicated for:

- Symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute pain
- Symptomatic relief of acute pain
- Symptomatic relief of post-operative 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)

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

510(k) Number K081255