

K071869

**Section 5: 510(k) Summary**

MAR - 7 2008

The following information is provided as required by 21 CFR § 807.87 for the Mini Combo 510(k) premarket notification for and in accordance with FDA's "Guidance Document for Powered Muscle Stimulator 510(k)s", June 9, 1999 and "Guidance for Tens 510(k) Content", August 1994.

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the TENS/IF 14 is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices .

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Tampa, Florida 33619  
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Registration Number: 3003573572

**Contact:** Cherita James  
M Squared Associates, Inc  
719 A Street, NE  
Washington, DC 20002  
Ph: 202-546-1262 Ext 257  
Fax: 202-546-3848

**Date of submission:** July 3, 2007

**Proprietary Name:** TENS/IF 14

**Common Name:** Transcutaneous Nerve Stimulator for pain relief, Interferential  
Current Therapy

**Classification Status:** 21 CFR 882.5890

**Class:** II

**Product Code:** GZJ, LIH

**Panel:** Neurology

**Predicate Device:** K060246 INFREX by Johari Digital Healthcare, K021755 TENS TS1211 by Apex Medical, K952683 IF-4000 by Apex Medical

**Device Description:** The TENS/IF 14 is a combination TENS and Interferential device which delivers nerve stimulation by applying an electrical current to electrodes, which are attached on the patient's skin. The output and waveform is adjustable according to the intended treatment of patient. The stimulator has 2 output channels, accessed through jacks at the top of the housing, so that it may stimulate either 2 or 4 patient electrodes. The device may be powered by either 4 AA batteries or by an AC adapter, that when plugged into a wall outlet provides 6 VDC to the unit. A patient compliance timer can memorize 60 sets of operation records; the total record time is 999 hours.

**Intended Use:** The TENS/IF 14 is intended for use by or on the order of a physician for the symptomatic relief of chronic intractable pain and as an adjunctive treatment for the management of post-traumatic or post-surgical pain.

**Discussion of performance testing:** Testing performed in accordance with the accepted FDA requirements of IEC 60601-1-2, Medical Electrical Equipment, Part 1: General Requirements for Safety. Collateral Standard: Electromagnetic Compatibility-Requirements and Test, found the TENS/IF 14 passed all of the applicable tests.

Based on the output measurements, calculations, and safety testing/inspection; the TENS/IF 14 meets standard requirements with respect to electrical leakage current, electrode and lead wire safety, as well as output current and power density.

#### **Technological Characteristics and Substantial Equivalence**

Output specifications, device design, waveforms and programmability demonstrated the TENS/IF 14 to be substantially equivalent to the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAR - 7 2008**

EMSI

% M Squared Associates, Inc.  
Ms. Cherita James  
719 A Street, NE  
Washington, DC 20002

Re: K071869  
Trade/Device Name: TENS/IF 14  
Regulation Number: 21 CFR 882.5890  
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief  
Regulatory Class: II  
Product Code: GZJ, LIH  
Dated: January 22, 2008  
Received: January 24, 2008

Dear Ms. James:

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.

Page 2 – Ms. Cherita James

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 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

### Section 4: Indications for Use Statement

510(k) Number: To be assigned

Device Name: TENS/IF 14

Indications for Use:

Symptomatic relief of chronic intractable pain

Adjunctive treatment for the management of post-traumatic or post-surgical pain

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Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
 (21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Handwritten Signature]*  
 (Division Sign-Off)  
 Division of General, Restorative,  
 and Neurological Devices

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