510(k) Summary

Inspirstar IS02 Microcurrent Stimulator – TENS Device

1. Submitters Identification

a. Company Name:	Inspirstar Inc.
b. Company Address:	891 N. Naples Dr. Chandler, AZ 85226, USA
c. Contact Person:	Ning Wu, Vice President
d. Date of Summary Preparation:	January 20, 2006

2. Device Identification

a. Common Name:	Microcurrent Transcutaneous Electrical Nerve Stimulator (TENS) for pain relief
b. Trade Name:	Inspirstar IS02 Microcurrent Stimulator Note: There might be two-letter suffix added to the model name "IS02" during marketing, like IS02AA, IS02AB. The names with different suffix are only for marketing and destination purpose and are the same products.
c. Classification:	Class II
d. Product Code:	GZJ
e. Regulation Number:	882.5890

3. Device Description

Inspirstar IS02 Microcurrent Stimulator is a Microcurrent TENS device intended to be used for the symptomatic relief of chronic intractable pain. This product can generate low current intensity pulses at microampere level and frequency of pulses. The unit supports five pre-defined therapy programs. The current intensity, frequency, time, etc. are programmable by doctors.

4. Intended Use

Inspirstar IS02 Microcurrent Stimulator is intended to be used for the symptomatic relief of chronic intractable pain.

5. Legally Marketed Predicate Devices

Inspirstar IS02 Microcurrent Stimulator is substantially equivalent to the following predicate device. See Table 5-1 Predicate Devices.

Table 5-1 Predicate Devices

Device Name	Manufacturer	510(k) No.	Date Cleared
THERASTIM (also known as "Precision Micro")	Precision Electronics, Ltd.	K914813	12/31/1991
"ALPHA-STIM CS" ("Alpha-Stim 100" is registered as update.)	Electromedical Products, Inc.	K896948	02/23/1990

6. Substantial Equivalence Summary

Inspirstar IS02 Microcurrent Stimulator has the same indications for use as the legally marketed predicate device. Inspirstar IS02 Microcurrent Stimulator has same or comparable technological characteristics as the predicate device. Inspirstar IS02 Microcurrent Stimulator is substantially equivalent to legally marketed predicate devices.

7. Technological Characteristics

Inspirstar IS02 Microcurrent Stimulator has the same technological characteristics as all of the predicate devices. All are battery-powered, current source pulse generator devices with two output channels. Inspirstar IS02 Microcurrent Stimulator has very close waveforms and output characteristics including frequency, current intensity, wave slope, etc with Precision Micro ("THERASTIM") and has comparable waveforms and output characteristics with Alpha-Stim 100("ALPHA-STIM CS"). Inspirstar IS02 Microcurrent Stimulator and Alpha-Stim 100 are both software controlled. The user operating interfaces to setup values of frequency, current intensity, etc have some differences for three devices. But these differences do not affect the technology and do not affect the safety and effectiveness.

8. Performance Data

Inspirstar IS02 Microcurrent Stimulator conforms to applicable voluntary standards IEC 60601-1 for safety requirement, and IEC60601-1-2 for electromagnetic compatibility requirement. In addition, the software verification has been carried out according to FDA software guidance.

9. Conclusions

Inspirstar IS02 Microcurrent Stimulator is substantial equivalent to legally marketed predicative devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2006

Inspirstar Incorporated
c/o Regulatory Technology Services LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K060368
Trade/Device Name: Inspirstar IS02 Microcurrent Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: March 2, 2006
Received: March 3, 2006

Dear Mr. Job:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting 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): K060368

Device Name: Inspirstar IS02 Microcurrent Stimulator

Indications for Use:

Inspirstar IS02 Microcurrent Stimulator is intended to be used for the symptomatic relief of chronic intractable pain.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060368