K060158

510(k) Summary

Prepared 10-10-06
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Contact: Lewis Ward

OCT 13 2006

Trade Name: NET-2000 Microcurrent Stimulator
Common Name: Stimulator, Cranial Electrotherapy
Classification: 21 CFR 882.5800
Product Code: JXK

The NET-2000 Microcurrent Stimulator is a precision electronic instrument used for the treatment of anxiety, depression, or insomnia. The treatment is simple and can easily be self-administered.

The device consists of a microprocessor controller box and skin contact electrodes. The small controller box is a software controlled low-intensity output. Current ranges from 0-600 microamperes typically set at 0.5 Hz. Additional frequencies at 1.5 and 100 Hz are available for the physician's use. The waveform is a bipolar asymmetric rectangular shape. Duty cycle is 50% with a 0 net current. Timed treatment is set at 16.5 minutes.

The following comparison table demonstrates the NET-2000 equivalent to the predicate.

COMPARISON TABLE, Microcurrent Stimulator

Feature	NET-2000	Alpha-Stim 100
Indication	Treats anxiety, depression, and insomnia	Treats anxiety, depression, and insomnia
Classification	CES, Class III Prescription, 882.5800	CES, Class III Prescription, 882.5800
Contraindications	None	None
Power Source	9 volt battery	9 volt battery
510(k)	This submission	K903014
Size	3.25" x 2" x .14"	13.5cm x 6.4cm x 3.3cm
Weight	3 oz.	5.5 oz.
Current	0-600 microamperes	10-600 microamperes

Frequency	0.5, 1.5, 100 Hz	0.5, 1.5, 100 Hz
Waveform	Bipolar asymmetric rectangular waves 50% duty cycle, 0 net current	Bipolar asymmetric rectangular waves 50% duty cycle, 0 net current
Electrodes	Silver, self adhesive pads with conduction solution, clip style. Applied to ear lobes.	Silver, self adhesive pads with conducting solution, clip style. Applied to ear lobes.
Timer Treatment Settings	16.5 minutes	10, 20, 60 minutes and continuous

Performance testing is confirmed by a comparative testing to the Alpha-Stim 100 and demonstrates equivalence. Electrical safety is confirmed by testing and passing requirements under EN60601-1-2 and EN60601-1. Biocompatibility for the electrode patient contact is confirmed by testing.

The NET-2000 is safe and effective and does not introduce new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Auri-Stim Medical Inc.
% Mr. Lewis Ward
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, Colorado 80301

OCT 13 2006

Re: K060158
Trade/Device Name: Net-2000 Microcurrent Stimulator
Regulation Number: 21 CFR 882.5800
Regulation Name: Cranial Electrotherapy Stimulator
Regulatory Class: Class III
Product Code: JXK
Dated: January 16, 2006
Received: January 20, 2006

Dear Mr. Ward:

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,

Barbara Buchner
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) K060158

Device Name: NET-2000 Microcurrent Stimulator

Indications for Use:

Application of electrical current to the head to treat insomnia, depression, or anxiety.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K060158

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

510(k) Number K060158