DEC 5 2005

K052625

Section 5. 510(k) Summary

510(k) Summary

Submitter Information:

Kent Hoffman
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And Regulatory Affairs and Chief Technical Officer
BioniCare Medical Technologies Inc.
47 R. Loveton Circle
Sparks, MD 21152
(410) 472-1888

Date Prepared:

July 11, 2005

Name and Classification of Device:

Transcutaneous electrical nerve stimulator for pain relief, Class II, 21 CFR 882.5890, Product Code GZJ

Device:

BioniCare® Stimulator Model BIO-1000™

Predicate device:

BioniCare® Stimulator Model BIO-1000™, k030332 and k983228

Device Description:

The BIO-1000 is a portable, rechargeable, battery-operated dual-channel device that utilizes a voltage regulated output circuit to generate a spike-shaped monophasic pulse with an adjustable amplitude of 0-12 volts peak and repeating at a single fixed frequency of 100 ± 5 Hertz.
The device consists of electrodes, lead wires and a signal generator.

Statement of Intended use:

BioniCare® Stimulator Model BIO-1000™ is indicated for use as an adjunctive therapy in reducing the level of pain, and stiffness associated with pain, from rheumatoid arthritis of the hand.

Summary of technological characteristics of New Device Compared to Predicate Device:

The new device's signal generator is identical to that in k030332. The electrical connection to the glove electrode was slightly modified so that if the insulating outer glove is removed, the conductive middle glove becomes nonconductive. A garment was added through which the lead wires travel to simplify use of the device and mitigate any tangling inconvenience or extremely remote strangling hazard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

JUN - 8 2006

Kent Hoffman
Executive Vice President Research,
Development and Regulatory Affairs and
Chief Technical Officer
BioniCare Medical Technologies, Inc.
47 R. Loveton Circle
Sparks, Maryland 21152

Re: K052625
Trade/Device Name: BioniCare® Stimulator, Model BIO-1000™
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NYN
Dated: September 22, 2005
Received: September 23, 2005

Dear Mr. Hoffman:

This letter corrects our substantially equivalent letter of December 5, 2005.

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 (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 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 continue 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/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson, M.S.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Protecting and Promoting Public Health

Indications for Use

510(k) Number (if known): K052625

Device Name: BioniCare Stimulator, Model BIO-1000™

Indications For Use: The BioniCare Stimulator, Model BIO-1000™, is indicated for use as an adjunctive therapy in reducing the level of pain, and stiffness associated with pain, from rheumatoid arthritis of the hand.

Prescription Use ✓ 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)

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

510(k) Number K052625