K073438

510(k) Summary

Bio Protech, Inc.

1720-26, Taejang 2-Dong, Wonju
Medical Instrument Park
Woonju-Si, Gangwon-Do, Republic of Korea

FEB 7

Date: September 6, 2007

Contact: Mr. Kevin Han
Bio Protech USA, Inc.
17962 Sky Park Circle
Suite G
Irvine, CA 92614
Phone: 1-949-250-9950
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Trade Name: *PROSTIM 1000/2000*

Common Name: TENS

Classification Name: Transcutaneous Electrical Nerve Stimulator (TENS) for pain relief

Predicate Device Identification:
CFR21:882.5890
Product Code: GZJ
Device Class: II

Legally Marketed Device:

Company	*Product*	*510(k) #*
Biomedical Life Systems, Inc.	Electro-Nerve Stimulator TENS	K061476
Theratech, Inc.	TTech Model 200E+TENS	K021436
Johari Digital Healthcare Ltd.	Infrex	K060246

Description:
The *PROSTIM 1000/2000* are battery operated TENS units for pain control. User driven the units feature a wide array of output combinations. The user may set the timer for 15 minutes to 30 minutes or a continuous mode. They also feature three modes: B (Burst), N (Normal), and M (Modulation). The pulse rate, pulse width, and amplitude are adjustable.

The devices are supplied with electrodes and electrode leads(K 042301) and electrode leads, battery case and 9V battery, Instruction manual and carrying case.

Intended Use:

The *PROSTIM 1000/2000* is used for the symptomatic relief and management of chronic intractable pain and adjunctive treatment of post-surgical or post-traumatic acute pain. This is a prescription device and should be used under continued medical supervision.

Comparison to Predicate Devices

The PROSTIM 1000 and PROSTIM 2000 TENS units have similar intended use, technology, operating principles and modes of operations. Based on the predicate product comparison Bio Protech has determined that no new issues of safety and effectiveness have been raised with this 510(k) submission.

Safety Standards:

IEC 60601-1-2: 2001

IEC 60601-2-10: 2001

IEC 60601-1: 1988

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2008

Bio Protech, Inc.
% Underwriters Laboratories, Inc.
Mr. Ned Devine
333 Pfingsten Road
Northbrook, Illinois 60062-2096

Re: K073438
Trade/Device Name: PROSTIM 1000/2000
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stmulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: January 22, 2008
Received: January 23, 2008

Dear Mr. Devine:

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 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,

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): K073438

Device Name: PROSTIM 1000/2000

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K073438