K020180

MAR 2 1 2002

510(k) SUMMARY
Woodside Biomedical Inc. ReliefBand® Device
Models RB-DL, RB-EL, and RB-RL

SUBMITTER INFORMATION

A.	Company Name:	Woodside Biomedical, Inc.
B.	Company Address:	1915 Aston Avenue Carlsbad, CA 92008
C.	Company Phone: Company Fax:	(760) 804-6900 (760) 804-6925
D.	Contact Person:	Tom Grey Vice-President of Product Development Woodside Biomedical, Inc.
E.	Date Summary Prepared:	January 16, 2002

DEVICE IDENTIFICATION

A.	Classification Name:	Transcutaneous Nerve Stimulator
B.	Trade/Proprietary Name:	ReliefBand® Device
C.	Classification:	Class II (21 CFR 882.5890)
D.	Product Code:	GZJ

IDENTIFICATION OF PREDICATE DEVICE

The Woodside Biomedical, Inc. ReliefBand® device Models RB-DL, RB-EL, and RB-RL are of comparable type and are substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
ReliefBand® Device Models RB-2, RB-6, and RB-R (OTC)	Woodside Biomedical, Inc.	K982967	February 23, 1999
ReliefBand® Device Models WB-2L, WB-6L, and WB-RL (Rx)	Woodside Biomedical, Inc.	K994387	March 16, 2000

DEVICE DESCRIPTION

The ReliefBand® Device Models RB-DL, RB-EL, and RB-RL are non-invasive devices which are indicated for over the counter use in the relief of nausea and vomiting (NV) due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy. The devices are contained within a wristband, and provide relief through electrical stimulation of the nerves in the patient's wrist.

The devices can be worn on the ventral or palmar (i.e., inside) surface of either or both wrists, approximately 2 fingers breadth above the distal skin crease of the wrist joint, between the tendons of the palmaris longus and flexor carpi radialis muscles.

The ReliefBand® device Model RB-xL family has a user display that incorporates five blinking LEDs which are used to identify the intensity level (5 discrete LEDs, one for each intensity level), so that the patient can easily select the desired stimulation. Selection of the intensity level is performed via a pushbutton located on the user display, which controls the peak pulse amplitude of the electrical impulse and thereby determines the intensity of the stimulation. A sixth blinking LED is used to display the low battery indicator.

The ReliefBand® device Model RB-xL family is powered by two 3V lithium batteries. The batteries are not user replaceable in the disposable device model RB-DL, but are user

replaceable in the reusable device models RB-EL and RB-RL. The battery life for all models is specified to be 150 hours when used at setting 3.

INDICATIONS FOR USE

The ReliefBand® Devices are indicated for over the counter use in the relief of nausea and vomiting (NV) due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the ReliefBand® Device and the predicate device has been performed. The results of this comparison demonstrate that the ReliefBand® Device is equivalent to the marketed predicate device. The differences between the ReliefBand® Device Models RB-DL, RB-EL, and RB-RL and the predicate models are insignificant and do not affect the safety or effectiveness of the device.

PERFORMANCE DATA

The performance data indicate that the ReliefBand® Device Models RB-DL, RB-EL, and RB-RL are substantially equivalent to the predicate ReliefBand® Devices distributed under K982967 and K994387.

CONCLUSIONS

Woodside Biomedical, Inc. has demonstrated through its evaluation of the ReliefBand® Device Models RB-DL, RB-EL, and RB-RL that the devices are equivalent to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2002

Woodside Biomedical,Inc.
C/O Carol L. Patterson
Patterson Consulting Group
21911 Erie Lane
Lake Forest, California 92630

Re: K020180
Trade/Device Name: ReliefBand® Device Models RB-DL, RB-EL and RB-RL
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: GZJ
Dated: January 17, 2002
Received: January 18, 2002

Dear Ms. Patterson:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OTC INDICATIONS FOR USE

510(k) Number: K020180 (To Be Assigned By FDA)

Device Name: ReliefBand® Device Models RB-DL, RB-EL, and RB-RL

Indications For Use: The ReliefBand® device is indicated for use in the relief of nausea and vomiting due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓

(Per 21 CFR 801.109)

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

510(k) Number K020180