K994387

MAR 1 6 2000

SUMMARY OF SAFETY AND EFFECTIVENESS
Woodside Biomedical Inc. ReliefBand® NST™ Device
Models WB-2L, WB-6L, and WB-RL

SUBMITTER INFORMATION

A.	Company Name:	Woodside Biomedical, Inc.
B.	Company Address:	1915 Aston Avenue, Suite 102 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:	December 19, 1999

DEVICE IDENTIFICATION

A.	Generic Device Name:	Nerve Stimulation Therapy Device
B.	Trade/Proprietary Name:	ReliefBand® NST™ (Nerve Stimulation Therapy) Device
C.	Classification:	Class II
D.	Product Code:	GZJ and BWK

IDENTIFICATION OF PREDICATE DEVICE

Device	Manufacturer	510(k) No.	Date Cleared
ReliefBand, Models WB-2, WB-6, and WB-R	Woodside Biomedical, Inc.	K982436 K983907	October 8, 1998 December 9, 1999

DEVICE DESCRIPTION

The ReliefBand® NST™ Device Models WB-2L, WB-6L, and WB-RL are non-invasive nerve stimulation therapy devices, and are indicated for use in the treatment of nausea and vomiting (NV) due to chemotherapy, motion sickness, and pregnancy. The ReliefBand ® NST™ Device is indicated as an adjunct to antiemetics in reducing postoperative nausea (PON). The devices are contained within a wristband, and provide relief of NV and PON 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™ NST™ device Model WB-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™ NST™ device Model WB-xL family is powered by two commercially available 3V lithium batteries. These batteries are not user replaceable in the disposable 2 day (WB-2L) and 6 day (WB-6L) devices, but are user replaceable in the Reusable device (WB-RL). The battery life for the 2 day device is specified to be 50 hours when used at setting 3. The battery life for the 6 day and Reusable devices is specified to be 150 hours when used at setting 3.

SUBSTANTIAL EQUIVALENCE

The Woodside Biomedical, Inc. ReliefBand® NST™ device Models WB-2L, WB-6L, and WB-RL are of comparable type and are substantially equivalent to the predicate ReliefBand® NST™ device Models WB-2, WB-6, and WB-R (K982436 and K983907).

INDICATION FOR USE

The ReliefBand® NST™ Device is indicated for use in the treatment of nausea and vomiting (NV) due to chemotherapy, motion sickness, and pregnancy. The ReliefBand ® NST™ Device is indicated as an adjunct to antiemetics in reducing postoperative nausea (PON).

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the ReliefBand® NST™ Device and the predicate device has been performed. The results of this comparison demonstrate that the ReliefBand® NST™ Device is equivalent to the marketed predicate device.

PERFORMANCE DATA

The performance data indicate that the ReliefBand® NST™ Device Models WB-2L, WB-6L, and WB-RL are substantially equivalent to the ReliefBand® Devices distributed under K982436 and K983907.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2000

Woodside Biomedical, Inc.
Ms. Carol L. Patterson
c/o Patterson Consulting Group
21911 Erie Lane
Lake Forest, California 92630

Re: K994387
Trade Name: ReliefBand® NST™ Device Models WB-2L, WB-6L, WB-RL
Regulatory Class: II
Product Code: GZJ and BWK
Dated: December 24, 1999
Received: December 28, 1999

Dear Ms. Patterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for

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

Enclosure

INDICATIONS FOR USE

510(k) Number: K994387 (To Be Assigned By FDA)

Device Name: ReliefBand® NST™ Device Models WB-2L, WB-6L, and WB-RL

Indications For Use: The ReliefBand® NST™ Device is indicated for use in the treatment of nausea and vomiting (NV) due to chemotherapy, motion sickness, and pregnancy. The ReliefBand ® NST™ Device is indicated as an adjunct to antiemetics in reducing postoperative nausea (PON).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

NRO for CDRH

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994387

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)