K980333

SECTION 19: SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 18 1998

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

19.1 SUBMITTER INFORMATION

a.	Company Name:	Woodside Biomedical, Inc.
b.	Company Address:	1132 San Marino Dr. San Marcos, CA 92069
c.	Company Phone: Company Fax:	(760) 761-0907 (760) 761-0535
d.	Contact Person:	Tom Grey Vice-President of Product Development Woodside Biomedical, Inc.
e.	Date Summary Prepared:	January 26, 1998

19.2. DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	ReliefBand
b.	Classification:	Class II
c.	Product Code:	73BWK

19.3 IDENTIFICATION OF PREDICATE DEVICE

Device	Manufacturer	510(k) No.	Date Cleared
ReliefBand	Maven Laboratories	K961050	August 1, 1997

19.4 DEVICE DESCRIPTION

The ReliefBand® Model SW-111 is a non-invasive nerve stimulation therapy device, and is indicated for use in the treatment of nausea and vomiting (NV) due to chemotherapy, motion sickness, and pregnancy. The device is contained within a wristband, and provides relief of NV through electrical stimulation of the P6 acupuncture area on the patient's wrist.

This acustimulation wrist band can be worn on either hand on the ventral or palmar (i.e., inside) surface of the wrist, approximately 2-3 fingers breadth above the distal skin crease of the wrist joint between the tendons of the palmaris longus and flexor carpi radialis muscles.

There are three operating modes based on pulse amplitude modulation scheme:

Mode A: 2 second burst, 6 seconds off. This is the first setting in the 3 mode sequence.

Mode B: 4 second burst, continuous. This is the second setting in the 3 mode sequence.

Mode C: 2 second burst, continuous. This is the third setting in the 3 mode sequence.

There are six intensity levels present for each of the three operating modes, and the intensity setting determines the strength of the stimulation. The user display on the wristband identifies both the operating mode and intensity level, so the patient can select the desired stimulation. The wristband is powered by either three silver oxide batteries (type 392/IEC SR41, 1.5 V), or three zinc-air batteries (type 312/IEC PR41, 1.4V), and should not be immersed in water.

19.5 SUBSTANTIAL EQUIVALENCE

The Woodside Biomedical, Inc. ReliefBand is of comparable type and is equivalent to the predicate Maven ReliefBand (K961050).

19.6 INTENDED USE

The ReliefBand is indicated for use in the treatment of nausea and vomiting (NV) due to chemotherapy, motion sickness, and pregnancy.

19.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the predicate and legally marketed devices has been performed. The results of this comparison demonstrate that the ReliefBand is equivalent to the marketed predicate device.

19.8 PERFORMANCE DATA

The performance data indicate that the ReliefBand meets the functional requirements and specifications of devices used for acustimulation of the P6 point.

19.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist has been provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Carol L. Patterson
Consultant for Woodside Biomedical Inc.
Patterson Consulting Group, Inc.
18140 Smokesignal Drive
San Diego, California 92127

FEB 18 1998

Re: K980333
Trade Name: ReliefBand®
Regulatory Class: II
Product Codes: GZJ and BWK
Dated: January 27, 1998
Received: January 28, 1998

Dear Ms. Patterson:

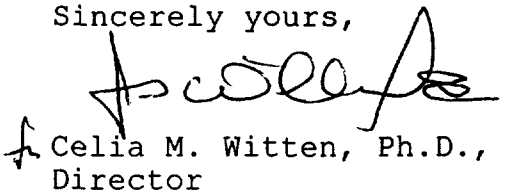
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 (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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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: To Be Assigned By FDA

Device Name: ReliefBand

Indications For Use: The ReliefBand is indicated for use in the treatment of nausea and vomiting (NV) due to chemotherapy, motion sickness, and pregnancy.

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 Devices
510(k) Number K980333

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)