

JAN - 7 2004

K033268

## 510(k) SUMMARY

### SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE SEA-BAND LTD SEA-BAND

#### SUBMITTER INFORMATION

|                           |   |
|---------------------------|---|
| Submitter Company Name    | Sea-Band Ltd  |
| Submitter Company Address | Sea-Band Ltd<br>Lancaster Road<br>Hinckley<br>Leicestershire LE10 0AW<br>England  |
| Submitter Telephone       | 011 44 1455 639750  |
| Submitter Facsimile       | 011 44 1455 639751  |
| Submitter Contact Person  | Neil R. Armstrong<br>Regulatory Affairs Advisor to Sea-Band Ltd<br>MeddiQuest Limited<br>Business & Technology Center<br>Bessemer Drive<br>Stevenage SG1 2DX<br>England<br>Telephone: 011 44 1763 222505<br>Fax: 011 44 1438 310001 |
| Date Summary Prepared     | August 15, 2003   |

#### DEVICE IDENTIFICATION

|                        |                   |
|------------------------|-------------------|
| Trade/Proprietary Name | Sea-Band          |
| Classification Name    | To be determined: |

Mr. Ted Stevens, D.G.R.N.D. Branch Chief at O.D.E. was contacted requesting a classification determination on April 09, 2002. This facsimile was treated as a 513(g) request for classification determination and passed to Mr. Steve Hinckley.

Since this time we have corresponded with Mr. Hinckley by e-mail, fax and telephone and in our latest telephone conversation (on 03/10/2003) Mr. Hinckley requested that we submit our 510(k) without Product Code, Regulation Number or Classification name.

## **DEVICE DESCRIPTION**

The "Sea-Band" consists of elasticated wrist band with a plastic button. The button is designed to apply pressure to the P6 or "nei-kuan", acupuncture point.

"Sea-Bands" are designed to be worn on each wrist and are supplied in pairs in a plastic case. The case is contained in an outer cardboard box with instructions for use.

The Sea-Band Ltd , Sea-Band will be available in a variety of different colors and pack types.

## **INDICATIONS FOR USE**

The Sea-Band Ltd "Sea-Band" is indicated for the relief of nausea.

(Nausea is a symptom that may be experienced due to a variety of causes, for example:

- Travel/Motion
- Pregnancy (Morning Sickness)
- Chemotherapy
- Post Operative)

## **TECHNOLOGICAL CHARACTERISTICS**

A comparison of the technological characteristics of the Sea-Band Ltd "Sea-Band" and the predicate devices has been performed.

The only significant difference in technological characteristic is between the Sea-Band Ltd "Sea-Band" and the Woodside Biomedical, Inc. "Relief Bands<sup>®</sup>". The "Relief Bands<sup>®</sup>" products use electrical rather than pressure stimulation, however FDA has already determined substantial equivalence of these two methods of nerve stimulation (PreMarket Notification submissions made by Maven Laboratories Inc. for the original Relief Bands).

## **PERFORMANCE DATA**

Published clinical evaluations, biocompatibility data and bench testing of physical properties of realtime age data demonstrate that the Sea-Band Ltd "Sea-Band" is safe and effective for its intended use and substantially equivalent to the predicate products.

Common/Usual Name  
Classification

See Classification Name above  
Class II

Ms. Gladys Rodriguez, Acting Director of Division of Enforcement III at the CDRH Office Compliance requested a 510(k) submission in her letter to Mr. Byron Chatburn, Managing Director of Sea-Band Ltd , of February 06 2002.

Product Code

See Classification Name above

### IDENTIFICATION OF PREDICATE DEVICE

Substantial Equivalence to Acu-Band K900588

The Sea-Band manufactured by Sea-Band Ltd is substantially equivalent to the Acu-Band by Euro Am Pharma Inc.

Substantial Equivalence to various ReliefBand<sup>®</sup> Products

The Sea-Band Ltd "Sea-Band" is also substantially equivalent to various "Relief Band" products manufactured by Woodside Biomedical, Inc.

| K Number | Product   |
|----------|---|
| K020180  | ReliefBand <sup>®</sup> Device Models RB-DL, RB-EL and RB-RL      |
| K994387  | ReliefBand <sup>®</sup> Device Models WB-2L, WB-6L, and WB-RL(Rx) |
| K983907  | ReliefBand <sup>®</sup> NST <sup>™</sup> Device Models WB-2L      |
| K982967  | ReliefBand <sup>®</sup> Device Models RB-2, RB-6 and RB-R (OTC)   |
| K982436  | ReliefBand <sup>®</sup> Device Models WB-2, WB-6, WB-R            |
| K980333  | ReliefBand <sup>®</sup> Device Model SW-111                       |

Substantial Equivalence to Other Products

Other similar products to the Sea-Band Ltd Sea-Band that are believed to have been marketed in the USA, and to which the Sea-Band may be substantially equivalent include:

Travel Smart by Victor Kiam –NoQweez Motion Discomfort Wrist Bands  
– also makes claims for Motion sickness.

Franzus Company Inc. 10 Railroad Ave. Beacon Falls, CT06403  
NoQweez is a Cirrus Air Technologies Trademark  
Model WVK-186NQ Made in USA Marketed by Wal Mart – box dated  
1998 Made in USA

TRAVEL BAND – Claims for Travel and M/Sickness  
Danelco Industries Ltd. 4 – 12880 Bayhgate Way Richmond, BC Canada  
V6V 1Z4

VALET – TRAVELAIDE WRISTBANDS –Motion Sickness  
Mayday Inc. 1121 Chesnut Street Burbank CA 91506 Tel.310 305 7500  
Made in USA

FIRST AID –EZY TRAVELER WRISTBAND – Motion Sickness  
Apothecary Products Inc. Minneapolis MN 55337 Made in USA

Davis – QUEAZ-AWAY Travelers' Wristbands  
David Instruments 3465 Diablo Ave. Haywood CA 945 45 Made in USA

Accu-Pressure BANDS – for travel  
Standard Merchandising Co. Camden NJ 08103 Made in USA

RISSBAND – Motion Sickness and Pregnancy  
Rissband Inc. 100 Spark Street Brockton MA 02402 Made in USA  
Copyright on leaflet 1989

TRAVELGARDE Acupressure Wrist Band  
Marine Logic Inc. 400 Australian Ave. Suite 725 West Palm Beach FL  
33401  
Tel 407 832 5112 Made in USA

BioBands – Morning Sickness - K822306  
BioBands Inc. NY 10010 Patent 5078728 Made in USA

MedicMates – Anti Sickness Bands for sea travel and morning sickness  
MedicMates Ltd GU1 2DT (UK) Made in USA

Acuband – Travel Sickness nausea – K900588  
AcuBand Ltd Suite 1B Market Centre Western International Market  
Hayes Rd. Southall Middlesex UK

THE TRAVELEZE – Travel Sickness  
The Traveleze PO Box 30 Blundell Lane Bursledon Nr. Southampton UK



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN - 7 2004

Sea- Band UK Ltd.  
C/o Mr. Neil R. Armstrong  
MeddiQuest Limited  
Business & Technology Center, Bessemer Drive  
Stevenage, Herts.  
United Kingdom SG1 2DX

Re: K033268

Trade/Device Name: Sea-Band Limited – “SeaBand”  
Regulation Name: Accu pressure device  
Regulatory Class: Unclassified  
Product Code: MVV  
Dated: September 1, 2003  
Received: October 9, 2003

Dear Mr. Armstrong:

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.

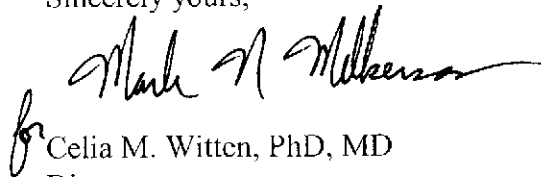
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Mr. Neil R. Armstrong

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 Office of Compliance at (301) 594-4659. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark A. Witten". The signature is written in a cursive style and is positioned above the typed name of the signatory.

for Celia M. Witten, PhD, MD

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): K033268

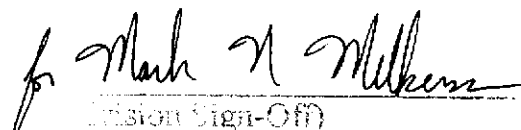
Device Name: Sea-Band Limited – "SeaBand"

Indications For Use:

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(Nausea is a symptom that may be experienced due to a variety of causes, for example:

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- Chemotherapy
- Post Operative)



Division Sign-Off  
Director of General, Restorative  
and Neurological Devices

510(k) Number: K033268

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)