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510K SUMMARY
RE: KO53509

AUG 16 2006

Submitter Information:

>Acuband Incorporated 101 Little Silver Point Road, Little Silver, NJ 07739

>Telephone: 732-219-9166

>Fax: 732-219-8972

>Contact Person: Richard Griffith

>Date Summary Prepared: July 18, 2006

Device Identification:

>Device name: Acuband

>Classification name: Acupressure wrist band

FDA Approved Predicate Devices:

> BioBands (K051397)

>Acu-Strap (K041877)

> Sea-Band (K033268)

> Ezy-Travel Band (K041766)

Device Description:

>The Acubands consist of a pair of wrist bands with a half-round button affixed to the interior side of the band. The Acubands are made of hook and loop fabric which allows the wrist band to be fully adjustable. The Acuband wrist bands enable the button to apply gentle pressure on the acupressure point, the P6 or Nei-Kuan, point on the inner wrist. This action interrupts the signal that triggers nausea.

Intended Use:

>Acubands are indicated for the relief of nausea. Nausea is a symptom which can be experienced by causes such as motion sickness, morning sickness (pregnancy), chemotherapy and post-operative from anesthesia.

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Technological Characteristics:

>The Acubands are constructed in the same manner as Bio-Bands (K051397). The Acubands utilize velcro hook and loop fabric for the band material which allows each band to be fully adjustable. The Acubands are sold as a pair and 1 band is intended to be worn on each wrist. The plastic button, located on the center of the interior side of the Acuband, is similar to the buttons in dimension and composition as the following predicate devices: Bio-Bands (K051397); Acu-Strap (K041877); Sea Band (K033268).

>The Acuband wrist band is substantially equivalent to the predicate products in terms of intended use, materials, dimension and mechanical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2006

Acuband, Inc.
c/o Mr. Richard Griffith III
President
101 Little Silver Point Road
Little Silver, New Jersey 07739

Re: K053509
Trade Name: Acuband™
Regulatory Class: Unclassified
Product Code: MVV
Dated: August 1, 2006
Received: August 15, 2006

Dear Mr. Griffith:

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 Office of Compliance at (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Little Silver NJ 07739
Phone 800-831-8777
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INDICATIONS FOR USE

510(K) Number: KO53509

Device Name: ACUBAND

Indications for Use:

Acubands are indicated for the relief of nausea. Nausea is a symptom which can be experienced by causes such as motion sickness, morning sickness (pregnancy), chemotherapy and post operative from anesthesia.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

And/Or

Over-the-Counter Use X
(21 CFR 801 Subpart C)

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

510(k) Number K053509