OCT 8 - 2004

510(k) Summary for
Acu-Strap™ Travel and Motion Sickness Band
K041877

1. SPONSOR

Health Enterprises, Incorporated
90 George Leven Drive
North Attleboro, MA 02760
(508) 695-0727

Contact Person: Glenn Leman, Chief Executive Officer

2. DEVICE NAME

Proprietary Name: Acu-Strap Travel and Motion Sickness Band
Common/Usual Name: Motion sickness band
Classification Information:

Motion sickness bands have not yet been classified by FDA, but have been given the following classification name and product code:

Name	Product Code	21 CFR Ref.	Panel
Acupressure device	MVV	To Be Determined	Neurology

3. PREDICATE DEVICES

Acu-Strap™ Travel and Motion Sickness Band is substantially equivalent to the Sea-Band, 510(k) No. K033268.

4. DEVICE DESCRIPTION

The Acu-Strap™ Travel and Motion Sickness Band product comprises a pair of wristbands, each with a round button added to the interior face of the band. Because the Acu-Strap™ Travel and Motion Sickness Band is stretchable, it will be sold in only one size. The Acu-Strap™ Travel and Motion Sickness Band operates by placing a constant pressure on an acupressure point (the P6 or "Nei-Kuan" point) near the wrist.

5. INTENDED USE

The Acu-Strap™ Travel and Motion Sickness Band is intended for the relief of nausea. Nausea may be experienced due to Travel (Motion Sickness), Pregnancy (Morning Sickness), Anesthesia or Chemotherapy.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Acu-Strap™ Travel and Motion Sickness Band is made of a stretchable fabric material with a hard plastic button that is snapped in place during manufacturing process. It is similar to the predicate device in terms of dimensions, materials, and mechanical characteristics.

7 PERFORMANCE TESTING

Acu-Strap™ Travel and Motion Sickness Band has been subjected to testing for dimensions, elasticity, and relative pressure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 - 2004

Health Enterprises, Inc.
C/o Mr. Daniel J. Dillon
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K041877
Trade/Device Name: Acu-Strap™ Travel and Motion Sickness Band
Regulatory Name: Acupressure Device
Regulatory Class: Unclassified
Product Code: MVV
Dated: September 20, 2004
Received: September 22, 2004

Dear Mr. Dillon:

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 (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

Indications for Use

510(k) Number (if known): K041877

Device Name: Acu-Strap™ Travel and Motion Sickness Band

Indications for Use:

The Acu-Strap™ Travel and Motion Sickness Band is intended for the relief of nausea. Nausea may be experienced due to Travel (Motion Sickness), Pregnancy (Morning Sickness), Anesthesia or Chemotherapy.

Prescription Use _____ AND/OR Over-the-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

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

510(k) Number K041877