PsiBands™

Another healthy product from Psi Health Solutions Inc.

510(k) Summary

JUL 26 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMVDA 1990 and 21 CFR §807.92.

510(k) number: K070766

1. Submitter's Identification:
Psi Health Solutions, Inc.
606 Lighthouse Avenue, #168
Pacific Grove, CA 93950
Contact: Romy Taormina
Co-Founder/Treasurer/Secretary
Date Summary Prepared:

2. Name of the Device:
Psi Band

3. Predicate Device Information:
Acuband Acupressure Wrist Band Device
Acuband Inc.
101 Little Silver Point Road
Little Silver, Nj 07739
510(k) number: K053509

4. Device Description:

Psi Bands, acupressure (pressure stimulation) wrist bands, consist of a plastic orb that applies pressure to the Nei-kuan (P6) acupressure point, the area that provides nausea relief. Psi Bands may be worn on both wrists at the same time and may be adjusted at two areas: 1) around the wrist like a watch, and 2) at the acupressure point by turning a plastic dial clock-wise. The plastic dial allows the user to apply different degrees of pressure at the acupressure point for maximum comfort and effectiveness. Select from one of three settings (mild nausea = low pressure; moderate nausea = medium pressure; troublesome nausea = high pressure). By turning the dial past the highest setting, the dial will automatically return to its neutral, or lowest, setting so that it cannot be over-tightened.

Psi Bands are made from synthetic rubber, specifically medical grade Santoprene™ thermoplastic rubber and food grade ABS plastic which does not directly contact the patient after adjustment. Cytotoxicity, primary skin irritation, and sensitization testing of

Santoprene™was performed by the manufacturer in accordance and compliance with Internal Organization for Standardization 10993 (See Biocompatibility Section). A Material Safety Data Sheet for the ABS plastic used in the button is attached (See Biocompatibility Section)

Psi Bands are offered in a variety of different colors and pack types.

Components of the system include:

Strap and collar made of medical grade Santoprene™ thermoplastic rubber
Button is composed of three parts; the dial, the nut and the ring all made of food grade ABS plastic and which reside inside the button itself which is part of the Santoprene™strap (See Device Description Section)

5. Intended Use:

Psi Bands are indicated for the relief of nausea.
Nausea is a symptom that may be experienced due to a variety of causes, for example:

- pregnancy (morning sickness)
- motion sickness
- anesthesia
- chemotherapy.

Psi Bands are intended for over-the-counter use

The publications supporting the use of Psi Bands for relief of nausea resulting from the four causative factors listed above were cited and their conclusions discussed in the Substantial Equivalence Section. These references therefore support the indications for use claimed for PsiBands.

AccuBand wrist bands, the predicate device, are claimed to relieve nausea resulting from the four causative factors listed above. Therefore the intended use of the Psi Band and the predicate device are equivalent.

6. Comparison to Predicate Device:

Technical characteristics of the device(s) compared to the predicate device:

	SUBJECT DEVICE	PREDICATE DEVICE
Feature	**PSI Band**	**Acuband**
510(k) Number	K070766	K053509
Intended Use	Relief of Nausea Caused by Morning Sickness (pregnancy), Motion Sickness, Anesthesia, and Chemotherapy	Relief of Nausea Caused by Morning Sickness (pregnancy), Motion Sickness, Anesthesia, and Chemotherapy
Length	9.33 inches	10.6 inches
Width	0.6 inches	0.8 inches
Wrist Circumference Limit	8.25 inches	8.5 inches
Band Composition	Santoprene™ thermoplastic rubber and medical grade ABS plastic	Nylon Hook and loop fabric (Velcro™) strap, Acrylic Button and a Polypropylene buckle
Pressure Adjustment	Yes, Adjustable	Yes, Adjustable
Button Composition	ABS Plastic Covered by Medical Grade Santoprene™ Thermoplastic	Acrylic Plastic
Band Elasticity	Non-elastic	Non-elastic
Typical Button contact area	0.13 square inches	0.12 square inches
Button Dimensions (Diameter)	0.40 inches	0.55 inches
Minimum contact pressure	0 pounds per square inch	0 pounds per square inch
Typical contact pressure	5-7 pounds per square inch	5-7 pounds per square inch

Table 1. Summary

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The performance outputs of the Psi Band and the predicate device, i.e., contact area and pressure exerted on the P6 (Nei-guan) pressure point were compared by bench testing.

Conclusions: The performance outputs of the subject device and the predicate device are equivalent.

8. Discussion of Clinical Tests Performed:

Not applicable. No clinical tests were performed.

9. Conclusions:

The subject device has the same intended use and similar characteristics as the predicate device. Moreover, documentation supplied in this submission demonstrates that any differences in their technological characteristics or materials do not raise any new questions of safety or effectiveness. Thus, the Psi Band is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2007

Psi Health Solutions, Inc.
% Ms. Romy Taormina
Co-Founder/Treasurer/Secretary
606 Lighthouse Ave #168
Pacific Grove, CA 93950

Re: K070766
Trade/Device Name: Psi Bands
Regulation Name: Device, Acupressure
Regulatory Class: unclassified (pre-ammendment)
Product Code: MVV
Dated: June 11, 2007
Received: June 13, 2007

Dear Ms. Taormina:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
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): K070766

Device Name: PsiBands

Indications For Use:

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- Pregnancy (morning sickens)
- Motion sickness
- Anesthesia
- Chemotherapy

Psi Bands are intended for over-the-counter use.

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)

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

510(k) Number K070766