K110821

FEB 27 2012

510(k) SUMMARY

Doodlebug Products's Barf Band

Date Prepared:

1/30/2012

Name of Device and Name/Address of Sponsor

Doodlebug Barf Band

Doodlebug Products
1809 Rockmoor Ave
Austin, Tx 78703
Phone: 615-400-0032

Common or Usual Name:

Barf Band

Classification Name:

Acupressure Device

Predicate Devices

PSI Band by Psi Health Solutions, Inc.

Sea Band by Sea-Band Limited

Intended Use / Indications for Use

The Barf Band is indicated for use in: The Barf Band is 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 and chemotherapy.

Technological Characteristics

The Barf Band is a wristband with adjustable properties that operates by putting pressure on Nei Kuan acupressure point (also known as the P6 point) on each wrist by means of a plastic dome/stud. The P6

K110821

point is located just below the bottom finger (index) in-between the two tendons. One band must be worn on each wrist to be effective.

Barf Bands are made from PVC free polyurethane, ABS plastic covered with Santoprene and 100% cotton. The band itself is composed of polyurethane. The ABS plastic covered with Santoprene is used to construct the plastic dome/stud that applies the pressure to the P6 point. The cotton is used inside the band to make the band comfortable to the end user.

Substantial Equivalence

The Barf Band is as safe and effective as the PSI Band (K070766) and Sea Band (K033268). The Barf Band has the same intended uses and indications for use, similar technological characteristics, and same principles of operation as its predicate device. The minor technological differences between the Barf Band and its predicate devices (e.g., dimensional and material composition) raise no new issues of safety or effectiveness. Performance testing conducted on the Barf Band and the predicate devices supports this. The force applied by the Barf Band wristband falls within the range established by the predicate devices. Thus, the Barf Band is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Doodlebug Products, LLC
c/o Barry E. Sands
RQMIS Inc.,
President
5 Hemingway Lane,
West Newbury, MA 01985

Re: K110821
Trade/Device Name: Barf Band
Regulation Number: none
Regulation Name: n/a
Regulatory Class: unclassified
Product Code: MVV
Dated: January 30, 2012
Received: January 31, 2012

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Dear Mr. Sands:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keva Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): NA K110821

Device Name: Barf Band

Indications for Use:

The Barf Band is 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 and chemotherapy.

Prescription Use _____ AND/OR Over-The-Counter Use_X_
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

Page 1 of 1

510(k) Number K110821