



NOV 29 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sleep Devices, Inc.
c/o Najeeb A. Zuberi, M.D.
President and CEO
720 West Oak Street, Suite 210
Kissimmee, FL 34741

Re: K040161

Trade/Device Name: Sona Pillow
Regulation Number: 872.5570
Regulation Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulatory Class: Class II
Product Code: MYB
Dated: April 19, 2004
Received: April 23, 2004

Dear Dr. Zuberi:

This letter corrects our substantially equivalent letter of April 30, 2004 regarding the Sona Pillow regulatory classification. At the time of that letter, FDA incorrectly classified the Sona Pillow, as indicated, as an unclassified device. This device is classified under 872.557, Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea. The product code will remain as MYB.

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 (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.

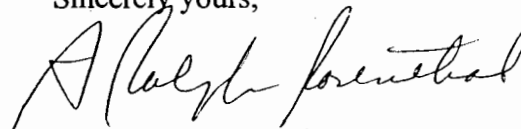
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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) 276-0115. 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. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

SONA PILLOW ,

INDICATIONS OF USE

510 K 040161
DATED: 4-16-04

THESE ARE THE INDICATIONS OF USE OF THE SONA PILLOW;

- 1- MAY STOP OR DECREASE SNORING
- 2- MAY BE USED TO TREAT MILD OBSTRUCTIVE SLEEP APNEA
- 3- MAY IMPROVE THE QUALITY OF SLEEP



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K040161

Over-the-Counter Use 