K100160

Exhibit 1 510(k) Summary

MAY 11 2010

1 510(k) Summary

Date of Summary Preparation: May 7, 2010

1.2 Submitter: Joseph Crocetti, DO
Sleep Specialists, LLC
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1.3 Trade Name: ZZOMA Positional Sleeper

1.4 Classification Name, Product Code, Class, Classification Reference:

Classification Name	Common Name	Product Code	Class	21CFR §
	ZZOMA Positional Sleeper	MYB	II	872.5570

1.5 Standards/Special Controls:

None

1.6 Indications for Use:

The ZZOMA Positional Sleeper is indicated for use and intended for professional use for the treatment of mild to moderate obstructive sleep apnea (OSA) and to reduce or alleviate snoring.

The ZZOMA Positional Sleeper is intended for use by professional healthcare personnel trained in its use.

1.7 Device Description:

The ZZOMA Positional Sleeper is 12 x 5.5 x 4 inches in size and made of lightweight semi-rigid synthetic foam (Figures 1 and 2). It is contained in a backpack type material with an associated Velcro® elastic belt. The device is worn on the back, with the elastic belts brought around each side of the subject and secured anteriorly with the adjustable straps. The particular size and wedge-shaped design on both sides of this device keeps the subject comfortably positioned on their side, and prevents him/her from assuming the supine position. The ZZOMA has a firm inner core made of foam and the outer part of the device is covered in nylon, and the part that touches the subject's body is cotton covered with a coating of PVC dots that help keep the ZZOMA in place while you sleep.

1.8 Substantially Equivalent Commercially Available Devices:

The ZZOMA Positional Sleeper device is substantially equivalent to the predicate device described herein with respect to indications for use:

Sleep Devices, Inc, Sona Pillow – K040161
Aeolus International Corporation, Sniff Position Pillows/Popitz Pillows - K023010

The predicate devices (Sona Pillow and Sniff Position Biollows/Popitz Pillows) are commercially available and marketed Class II devices.

1.9 Substantial Equivalence Comparison:

INDICATIONS FOR USE

ZZOMA Positional Sleeper	**Predicate** Sleep Devices, Inc, Sona Pillow – K040161	**Equivalency**
The ZZOMA Positional Sleeper is indicated for use and intended for non-professional, over-the-counter use and for professional use for the treatment of mild to moderate obstructive sleep apnea (OSA) and to reduce or alleviate snoring.	May stop or decrease snoring May be used to treat mild obstructive sleep apnea May improve the quality of sleep	Same – Treats mild obstructive sleep apnea Same – regarding effects on snoring Different – does not disrupt sleep quality Different – treats both mild and moderate sleep apena

METHODOLOGY

ZZOMA Positional Sleeper	**Predicate**	**Equivalency**
Positions on the back	Positions on the head and neck	Same – both devices prevent subjects from sleeping on their backs Different – Pillow positions head, Zzoma positions back

PERFORMANCE

Item	**ZZOMA Positional Sleeper**	**Predicate**	**Equivalency**
Storage	Room temperature	Room temperature	Same
Positioning	Keep subject off back while sleeping	Keep subject off back while sleeping	Same

A clinical study was conducted to examine the non-inferiority of the Zzoma Positional Sleeper and CPAP therapy on the apnea-hypopnea index after one night of therapy in patients with positional obstructive sleep apnea.

A secondary objective was to evaluate the ability of the Zzoma Positional Sleeper to maintain the patient in the lateral position during sleep. Another secondary objective is to evaluate the initial effects of the Zzoma Positional Sleeper on nocturnal oxygenation, and compare it to initial effects seen with CPAP therapy.

There were 4 major findings in this study: 1) in patients with positional OSA, positional therapy is equivalent to CPAP therapy at normalizing the AHI to < 5 events/hr in addition to decreasing the AHI by > 50%, 2) positional therapy is similar to CPAP therapy in regards to effects on sleep quality and nocturnal oxygenation, 3) there is minimal night-to-night variability in the non-supine AHI in patients with positional OSA, and 4) that our PD is effective at maintaining patients in the non-supine position throughout the night.

1.10 Indications and Contraindications:

Relative indications and contraindications for the ZZOMA Positional Sleeper and positional commercially available devices for similar intended uses (treating moderate positional sleep apena) are similar.

1.11 Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, Sleep Specialists, LLC concludes that the new device, ZZOMA Positional Sleeper, is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY 11 2010

Sleep Specialists, LLC
c/o Mr. Howard Mann
1 Congressional Drive, Apt C
Greenville, Delaware 19807

Re: K100160
Trade/Device Name: ZZOMA Positional Sleeper
Regulation Number: 21 CFR 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: March 29, 2010
Received: April 6, 2010

Dear Mr. Mann:

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,

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

Enclosure

K100160

EXHIBIT B Indications for Use Statement

Indications for Use

510(k) K100160:

Device Name: ZZOMA Positional Sleeper

Indications for Use:

The ZZOMA Positional Sleeper is indicated for use and intended for professional use for the treatment of mild to moderate, predominantly positional obstructive sleep apnea (OSA) and to reduce or alleviate snoring.

The ZZOMA Positional Sleeper is intended for use by professional healthcare personnel trained in its use.

Caution: Federal law restricts the device to sale by or on the order of a physician or dentist.

Prescription Use X **AND/OR** **Over-The-Counter Use**
(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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K100160