MAR - 1 2012 K113569





*6. 510(k) Summary*

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

| | |
|---|---|
| APPLICANT: | **Apnea Sciences Corporation**<br>Apnea Sciences<br>27071 Cabot Road Building #118<br>Laguna Hills, California. 92653<br>Phone - 949 226 4421<br>Fax – 928 569 5974 |
| CONTACT : | Gary Mocnik<br>49 Coastal Oak, Aliso Viejo, CA 92656<br>949.433.0413<br>949.831.9944 fax<br>gmocnik@cox.net |
| DATE PREPARED | November 30, 2011 |
| TRADE NAME: | ApneaRx |
| COMMON NAME: | Oral Appliance for Mild to Moderate Sleep Apnea & Snoring |
| CLASSIFICATION NAME: | Oral Appliance, 21 CFR, 872.5570 |
| DEVICE CLASSIFICATION: | Class II |
| PRODUCT CODE | LRK |
| PREDICATE DEVICES: | Consumer Health Products "SnoreRx" (K112205), Respironics Custom 1, (K033822) SnoreFree (K955336), OSAP, (K960673), SnoreMaster (PureSleep) (K954128). |

**Substantially Equivalent To:**
The Apnea Sciences Corporation ApneaRx is substantially equivalent in intended use, principal of operation and technological characteristics to the Consumer Health Products "SnoreRx (K112205), Respironics "Custom 1" (K033822), SnoreFree (K955336), OSAP, (K960673), SnoreMaster (PureSleep) (K954128), as well as other predicate devices cleared with an LRK Product Code.

**Description of the Device Subject to Premarket Notification:**
The Apnea Sciences Corporation ApneaRx is an intraoral device used at night to reduce mild to moderate obstructive sleep apnea, and/or snoring by advancing the lower jaw (mandibular repositioning) and thereby minimizing air obstruction and turbulence. The device consists of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth. This interface, and thus this device, functions as a mandibular anterior repositioner, which acts to increase

the patient's pharyngeal space, improving the ability to exchange air during sleep

**Indication for Use:**

The Apnea Sciences Corporation "ApneaRx" is intended for use on adult patients 18 years of age or older as an aid for the reduction of mild to moderate obstructive sleep apnea, and/or snoring.

**Discussion of Technical Characteristics:**

The Apnea Sciences Corporation ApneaRx has similar physical and technical characteristics to the predicate devices. The Apnea Sciences Corporation ApneaRx and the identified predicates all provide means for advancing the lower jaw in a predetermined manner. The technical designs and manufacture of the ApneaRx and the predicate devices are very similar, being composed of custom fitted co polymer / trays which fit onto the upper and lower teeth and which are positioned in relation to each other by an adjustable mechanism.

**Non-Clinical Performance Data:**

Performance testing was conducted to evaluate and characterize the performance of the Apnea Sciences Corporation ApneaRx. Preclinical testing conducted included dimensional conformance evaluation, visual inspections, design verification to confirm airway passage equivelancy and biocompatibility testing based on the applicable elements of ISO 10993-1 shown below.

| Test Performed | Standard | Test Result/Conclusion |
|---|---|---|
| ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells | ISO 10993-5 | Passed.<br>Non-cytotoxic |
| ISO Intracutaneous Irritation Test | ISO 10993-10 | Passed.<br>Non-irritant |
| Sensitization: Guinea Pig Maximization | ISO 10993-10 | Passed/Negative for evidence of sensitization |

Additionally material characterization testing was performed and concluded that the materials used in the construction of the Consumer Health Products Apnea Rx are identical the listed predicate device.

**Clinical Data**

This submission does not rely on clinical data to determine substantial equivalency to the predicate devices.

## Section 6 510(k) Summary

**Basis for Determination of Substantial Equivalence:**

**Conclusions Drawn:**

| Product | Intended Use | Principle of Operation | Overall Technological Characteristics |
|---|---|---|---|
| **Apnea Sciences Corporation ApneaRx** | The Apnea Sciences Corporation "ApneaRx" is intended for use on adult patients 18 years of age or older as an aid for the reduction of mild to moderate obstructive sleep apnea, and/or snoring | Provides for mandibular repositioning to increase pharyngeal space | Custom fitted plastic intraoral device inserted over the upper and lower dental arches. |
| Consumer Health Products SnoreRx NS 9.0 (K112205) | The Consumer Health Products "SnoreRx NS 9.0" is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring." | SAME | SAME |
| SnoreMaster PureSleep (9541285) | The anti-snoring device is intended to alleviate or correct snoring | SAME | SAME |
| Respironics "Custom 1", (K033822) | The Respironics Custom I Oral Appliance is intended for use by a dentist on adult patients as an aid for the reduction or elimination of snoring and obstructive sleep apnea. | SAME | SAME |
| SnoreFree (K955336) | Intended to treat mild to moderate obstructive sleep apnea (OSA) and snoring in adults 18 years of age or older only. | SAME | SAME |
| OSAP, (K960673). | Intended to treat mild to moderate sleep apnea, OSA and snoring in adults 18 years of age or older. | SAME | SAME |

As shown, the Apnea Sciences Corporation ApneaRx has the following similarities to the predicate devices:

- Same intended use
- Same design characteristics
- Same operating principal
- Same mechanism of action
- Same technological characteristics

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Apnea Sciences Corporation ApneaRx is determined by Apnea Sciences Corporation, to be substantially equivalent to existing legally marketed devices

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

Apnea Science Corporation
C/O Mr. Gary Mocnik
Regulatory Consultants
Gary Mocnik and Associates
49 Coastal Oak
Aliso Viejo, California 92656

MAR - 1 2012

Re: K113569
Trade/Device Name: ApneaRx
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: November 30, 2011
Received: December 2, 2011

Dear Mr. Mocnik:

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,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

*5. Indications for Use Statement*

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113569

Device Name: ApneaRx

Indications for Use:

The Apnea Sciences Corporation "ApneaRx" is intended for use on adult patients 18 years of age or older as an aid for the reduction of mild to moderate obstructive sleep apnea (OSA), and/or snoring.

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

---

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

OR

Prescription Use __X__ (Per 21 CFR 801.109)

Over-The-Counter Use_____ (Optional Format 1-2-96)

Page __ of ___

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K113569