K112766

JUN - 4 2012

510(k) SUMMARY

Date Prepared: August 01, 2011. Updated: April 12, 2012
Submitter Information:

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Device Information:

Trade Name:	The Snorkel, Jaw Repositioning Device, K112766
Common Name:	The Snorkel
Classification Name:	Mandibular Repositioning Device
Product Code:	LQZ
Regulation:	21 CFR 872.5570

Device for which Substantial Equivalence (SE) is claimed:

Common Name:	Adjustable PM Positioner, K955503
Classification Name:	Mandibular Repositioning Device
Product Code:	LQZ
Regulation:	21 CFR 872.5570

Like the Adjustable PM Positioner (K955503), the Snorkel is a mouth splint appliance comprised of an acrylic upper body and an acrylic lower body, which are coupled together to push the lower jaw forward. The Snorkel is intended for use in patients, for the reduction of snoring and to treat mild to moderate obstructive sleep apnea.

DEVICE DESCRIPTION

The Snorkel is an oral mandibular advancement device whose function is to artificially protrude the chin (mandible) forward so as to pull the tongue away from the back of the throat, thereby reducing tongue-induced airway obstruction.

The Snorkel device is custom-made and fitted based on dental impressions and used by the patient during sleep. The single mouth piece fits snugly onto the upper and lower crowns of the patient's teeth. As the patient falls asleep, thus relaxing their mandible, a silicon band provides tension such that the mandible is pulled forward along with the tongue.

INDICATIONS FOR USE

The Snorkel is used to reduce tongue induced airway obstructions. The Snorkel is intended for use in patients, for the treatment of mild to moderate obstructive sleep apnea.

SUMMARY OF NON-CLINICAL TESTING

The non-clinical testing included assessment of the physical properties of the SNORKEL and its ability to achieve its intended use. The Snorkel meets the same specifications as set for the predicate device.

A biocompatibility assessment of the device was performed. The purpose of the biocompatibility assessment was to ensure that biocompatibility had been established for the device. The device is biocompatible, based on the similarity of the materials of construction to the predicate device (The Adjustable PM Positioner) marketed by Airway Management Inc.

SUMMARY OF CLINICAL TESTING

Human clinical studies were not deemed necessary to evaluate the safety or effectiveness of the Snorkel. The Snorkel does not: Use designs dissimilar from the predicate device and other previously cleared devices under a 510(k); The Snorkel does not use new technologies different from legally marketed intramandibular repositioning devices for snoring and/ or obstructive sleep apnea; and the Snorkel does not deviate from the indications for use identified in the predicate device: Adjustable PM Positioner.

In lieu of human clinical testing, the risks and mitigating controls associated with the use of mandibular repositioning devices, as identified by the FDA, have been addressed in the "Risk Assessment". In addition, adequate warnings and precautions are found in the "Instructions for Use" manual.

STATEMENT OF EQUIVALENCE

The Snorkel is substantially equivalent to the currently marketed Adjustable PM Positioner based on a comparison of the indications for use and the technological characteristics of the device. The only design difference is in the nature of the adjustable mechanisms in the two devices.

CONCLUSION

The Snorkel is substantially equivalent to the currently marketed Adjustable PM Positioner based on the indications for use, technological characteristics, and materials of construction and principals of operations of the device.

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

Mr. Wayne Marshall
Acting Manager
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JUN - 4 2012

Re: K112766
Trade/Device Name: The Snorkel
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: LQZ
Dated: May 8, 2012
Received: May 14, 2012

Dear Mr. Marshall:

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.

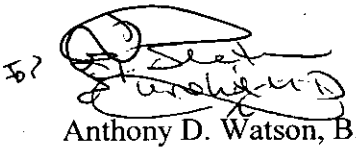
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

Indications for Use

510(k) Number (if known): K112766

Device Name: The Snorkel

Indications For Use:

The Snorkel is used to reduce tongue induced airway obstructions. The Snorkel is intended for use in patients, for the treatment of mild to moderate obstructive sleep apnea.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112766