K073004

510(K) SUMMARY

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

Submitter Information: SomnoMed Inc

JAN 30

Date Summary Prepared: 5th October 2007

Contact Persons: Ashley Truitt

Device Name:
Trade Name(s): **SomnoMed MAS Flex "S"**
Classification Name: **Device, Anti-snoring (21CFR827.5570)**
Panel: **Dental**
Product Code: **LRK**

Predicate Device Information:

Device Name	Manufacturer	510(k) Reference
SomnoMed MAS	SomnoMed Inc	**K050592**

Device Description:

The Somnomed MAS Flex "S" is an intra-oral device used for treating Snoring and mild to moderate Obstructive Sleep Apnea. It consists of two custom fitted trays which fit over the upper and lower teeth and engage by means of adjustable lugs. The device functions as a mandibular repositioner, which acts to increase the patient's pharyngeal space during sleep and improves their ability to exchange air during sleep. The device is custom made for each patient and has the adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device.

Intended use – The SomnoMed MAS Flex "S" is intended to reduce or alleviate night time snoring and mild to moderate obstructive sleep apnea.

Target population – Adult patients who have a problem with snoring or obstructive sleep apnea.

Environment of Use – The device is initially fitted under the supervision of a licensed practitioner (dentist or physician) and is subsequently used in either a home environment or in a sleep laboratory.

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Comparison to Predicate Device:

This submission is for a modification to the originally cleared SomnoMed MAS device.

The SomnoMed MAS Flex "S" is substantially equivalent to the SomnoMed MAS with the only exception of a soft lining material (SMH Flex "S") that can be used instead of the stainless steel ball clasps for retention. The difference between the two types of retention are that the soft lining material (SMH Flex "S") is technologically advanced to grip around the tooth creating a good retention which is designed for patient comfort, this negates the need for metal retention such as ball clasps.

Comparison Table of Predicate Devices				
Attribute	SomnoMed MAS (K050592)	OASYS (K030440)	TAP 401 (K062951)	SomnoMed Flex (S)
Indications for Use				
Treatment of Snoring in Adults	yes	yes	yes	Yes
Treatment of mild to moderate obstructive sleep apnea	yes	yes	yes	yes
Use				
Intra oral device for overnight use	yes	yes	yes	yes
Single patient multi use	yes	yes	yes	yes
Use at home or at a Sleep Laboratory	yes	yes	yes	yes
Prescription Device	yes	yes	yes	yes
Action				
Works by mandibular advancement	yes	yes	yes	yes
Design				
Custom fit for each patient	yes	yes	yes	yes
Rigid separate upper and lower tray pieces	yes	yes	yes	yes
Can be adjusted or refit	yes	yes	yes	yes
Lower jaw adjustment using a supplied adjustment key	yes	yes	yes	yes
Cleaned and inspected daily	yes	yes	yes	yes
Permits patient to breathe through the mouth	yes	yes	yes	yes
Upper and lower trays disengage for easy removal from mouth	yes	yes	yes	yes
Materials				
Trays constructed from molded hard acrylic and ball clasps	yes	**no**	**no**	**no**
Trays constructed from a soft lining material adhered to a hard surface acrylic	**no**	**no**	**no**	yes
Trays constructed from a heat sensitive impress able material for fitting to teeth	**no**	yes	yes	**no**

The difference between the intended device SomnoMed Flex "S" and the predicate devices are the materials. All of the predicates act as mandibular repositioners for the treatment of Snoring and mild to moderate Obstructive Sleep Apnea. This difference does not have significant effect on the safety or effectiveness of the SomnoMed MAS Flex "S". It is the prescribing physician's choice what material is used for the patients comfort and what is most suitable for the individual patient's dentition.

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Comparative performance testing was carried out with a previously cleared predicate material **Ivocap Elastomer K896130** that is used in the Orthodontic field for the fabrication of Tooth Positioners, Mouthguards and Soft Bite Guards.

Performance Test Data and Conclusions:

Bench testing has established material biocompatibility and product strength with the material SMH Flex "S".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2008

Ms. Ashley Truitt
SomnoMed Incorporated
3537 Teasley Lane
Denton, Texas 76210

Re: K073004
Trade/Device Name: SomnoMed MAS Flex "S"
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, EBI
Dated: December 15, 2007
Received: January 25, 2008

Dear Ms. Truitt:

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.

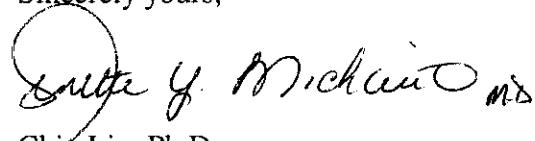
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 begin 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use K073004

510(k) Number (if known): 1081

Device Name: SomnoMed MAS Flex "S"

Indications for Use:

The SomnoMed MAS Flex "S" is intended to reduce or alleviate night time Snoring and mild to moderate Obstructive Sleep Apnea (OSA).

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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

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