DENTAL IMAGINEERS
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Concept, Development & Production
of Specialized Dental Technology

JUL 2 2 1999

K99 1449

510(k) Summary

April 21,1999

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phone: (732) 493-4747
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Device/Trade name: Snore-Aid®*plus*

Descriptive name: Mandibular Advancement and Tongue Positioning Orthotic (MATPO)

Common name: Anti-Snoring Device

Classification name: Device, Anti-Snoring

Substantial Equivalence Device: The Snore-Aid®*plus* is substantially equivalent to the Snore Free® K955336 (also known as the Rest Assured® appliance) and the Snore Guard® K882303 appliances.

Description of Device:
Snore-Aid®*plus* is a single plate mandibular advancement and tongue positioning orthotic consisting of: (1) a flat mandibular occlusal bite

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plate, (2) an adjustable external maxillary lip shield, and (3) a wide occlusal surface. The occlusal bite plate provides dental stability, protects the TMJ from occlusal loading and prevents muscle soreness due to bruxism. It also actively elevates and positions the tongue anteriorly and dorsally against the palate, thereby increasing the patency of the airway.

The Snore Free® and Snore Guard® utilize a single unit maxillary plate and a mandibular guide plane to advance the lower jaw. The Snore-Aid®*plus* utilizes the mandibular occlusal bite plate to hold the lower jaw forward and buttresses against the maxillary lip via the use of a maxillary external lip shield.

The external lip shield is adjustable horizontally upon an anterior extension of the occlusal bite plate which extends between the lips.

Intended Use:
Snore-Aid®*plus* is a perscribed anti-snoring device.

A. Snore-Aid®*plus* is indicated for use in patients with primary snoring or snoring and mild OSA (obstructive sleep apnea) where mandibular advancement and elevation of the tongue can increase a patient' s pharyngeal air space.

B. Snore-Aid®*plus* is indicated to prevent symptoms of nocturnal parafunctional jaw activity in patients undergoing treatment for snoring and OSA by mandibular advancement and tongue positioning.

Technological Characteristics:
The Snore-Aid®*plus*, Snore Free®, and Snore Guard® appliances are similar in that they all are individually customized and they all advance the lower jaw and increase airway space. The predicate devices have no means of actively elevating the tongue. However, Snore-Aid®*plus* elevates the tongue against the palate even if the mandible is not fully advanced, and thereby efficacy is enhanced.

Snore-Aid®*plus* and Snore Free® have full occlusal coverage to prevent occlusal bite changes. Moreover, the occlusal bite plate of Snore-Aid®*plus* can be equilibrated as a splint to influence occlusal function

and protect against parafunctional habits. SnoreGuard® has only partial occlusal coverage.

In the Snore Free® and Snore Guard® devices the maxillary plate and the mandibular guide plate provide the advancement function, but there is no protective mechanism for the TMJ. Snore-Aid®*plus* uses an external lip shield in lieu of the maxillary plate of the SnoreFree® and SnoreGuard®. It permits the mandible freedom of vertical and lateral motion. Furthermore, it allows the device to be adjustabled to fit different jaw sizes and it is a convenient means of titrating the mandibular advancement. SnoreFree® and SnoreGuard® require remolding in order to adjust the mandibular advancement and there is little if any freedom of lateral jaw motion.

Clinical Data:
Clinical testing of the Snore-Aid®*plus* (MAPTO) appliance was done on 25 subjects who were diagnosed with snoring and mild to severe OSA. Twelve channel polysomnography was used to test subjects during full night sleep studies which were done pretreatment and repeated 4 weeks post-treatment. Treatment success was defined as a 50% reduction in RDI and a post-treatment RDI≤ 10. In 18 of 18 patients who had an initial RDI ≤30 there was treatment success. In 7 individuals who had severe apnea (RDI > 30) all achieved a reduction in RDI which was below of the pretreatment index, but only one achieved a RDI≤10. In none of the subjects was there any indication of TMJ pain or muscle sorness. None of the subjects reported bite changes upon awakening from sleep. Two patients reported nocturnal bruxism which caused temporary soreness of incisor teeth.

Conclusion:
Snore-Aid®*plus* is appropriate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 1999

William A. Belfer, D.M.D., M.Sc.D.
Chief Executive Officer
Dental Imagineers & Associates
804 West Park Avenue
Ocean, New Jersey 07712

Re: K991449
Trade Name: Snore-Aid® plus
Regulatory Class: Unclassified
Product Code: LRK
Dated: April 21, 1999
Received: April 26,1999

Dear Dr. Belfer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Snore-Aid® *plus*

Indications For Use:

Snore-Aid®*plus* is prescribed for the patient by the healthcare professional.

A. Snore-Aid®*plus* is indicated for use in patients with primary snoring or snoring and mild obstructive sleep apnea (OSA) where mandibular advancement and positioning of the tongue can increase pharyngeal air space.

B. Snore-Aid®*plus* is indicated to prevent symptoms of nocturnal parafunctional jaw activity in patients undergoing treatment for snoring and OSA by mandibular advancement and tongue positioning.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K961447

(Optional Format 1-2-96)