K133683
JUL 24 2014

6 510(k) Summary

MicroDental Laboratories is hereby submitting a 510(k) Summary as per 21 CFR 807.92.

1. **Date Summary Prepared:** **November 15, 2013**
2. **Submitter Information:** MICRODENTAL, Inc.
   5601 Arnold Rd
   Dublin, CA 94568
3. **Contact Person:** Laura Sheppard
   Senior Director of Compliance and Regulatory
4. **Device Name:**

Proprietary/Trade name:	MicrO2 Obstructive Sleep Apnea Device
Common name:	Mandibular Advancement Device
Classification name:	Intraoral devices for snoring and mild to moderate obstructive sleep apnea
Device Classification:	II
Regulation number:	21 CFR 872.5570
Product code:	**LRK**

5. **Identification of Predicate Device(s)**

   Device Name: Somnomed MAS RXA
   Manufacturer: SomnoMed, Ltd.
   510(k) Number: K050592

   The predicate device has the same intended use and uses similar materials as the MicrO2 OSA device.

6. **Device Description:**

   The MicrO2 OSA device series consists of maxillary and mandibular devices that when interfaced together alleviate snoring and mild to moderate sleep apnea by holding the mandible forward during sleep, preventing the tongue and soft tissues of the throat from collapsing into the airway. These separate upper and lower arch devices are designed with twin-mated posts and are CAD/CAM generated specifically for each prescription. Designed as a patient-specific device, the MicrO2 series consists of one or multiple lower device(s) together with one or multiple mated-post upper device(s) that are manufactured to the dentist prescriber's requested advancement positions to provide a selection of gentle adjustments according to patient comfort and need. As such, prescribed advancements can be achieved by simply removing the current upper or lower device and inserting the next upper or lower device in the mandibular advancing series. The MicrO2 does not have any adjustment mechanisms to modify or

maintain the mandibular position such as pistons, screws, straps or repositioning elastics. The maximum protrusion of a MicrO2 archform is 6mm, which is comparable to the predicate device's 6mm advancement screw, measuring from plate to plate. This also negates the need for patients utilizing external controlling components such as keys, screwdrivers or ligature ties. The maximum protrusion of a MicrO2 archform is 6mm, which is comparable to the predicate device. The MicrO2's twin-mated post and lingualess design yields a small and a comfortable patient-specific mandibular advancement device. The design of the device maximizes tongue space and mandibular movement resulting in the ability to open and close during wear.
The Micr02 OSA device is identical to the Somnomed MAS RXA (Classic) except for the difference in the adjustment mechanism. Any differences introduced by these modifications when compared to the predicate device, do not introduce any new safety concerns.

7. **Indications for Use:**
The MICRODENTAL, Inc. MicrO2 device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

8. **Bench Testing in Support of Substantial Equivalence:**

The results of bench testing and pre-clinical testing support the above indications for use as well as the claim of Substantial Equivalence. The substantial equivalence was demonstrated through the materials that were used by the predicate devices as well as the technical and performance characteristics compared to the predicate. Compression and shear testing are important performance characteristics as they approximate the mechanical force applied by during normal use of the device. Bench testing results are listed in the table below. Multiple tests were performed to address fin fracture and arch framework fracture risks, evaluating the strength of the Micro2 device when a patient applies muscular forces during wear or physical forces during patient mishandling of the device. These tests were identified by Risk Analysis conducted in accordance with ISO-14971.

The MicrO2 OSA device uses the same materials as those in the predicate devices and is a well known material for dental applications. The material manufacturing processes between Micr02 OSA device and the predicate device are identical. No new chemicals or formulas have been introduced. As such, additional biocompatibility testing was not conducted. Monomer leachablity testing was performed and compared to the predicate device.

9. **Conclusions from Bench Testing**

The MicrO2 OSA device has completed all of the internal and standards testing above with acceptable results, demonstrating substantial equivalence to the referenced predicate. The subject under test performed as well or better than the predicate device, the Somnomed MAS RXA.

Test Design	Devices	Equal or Improved based on Mean Shear Strength (lbf)
AP Direction Fin Test	Somnomed MAS RXA	
	Micr02 OSA	Yes
Lateral Direction Fin Test	Somnomed MAS RXA	
	Micr02 OSA	Yes
Cross-Arch Compression Test	Somnomed MAS RXA	
	Micr02 OSA	Yes
Leachability Test* *Based on ug/g	Somnomed MAS RXA	
	Micr02 OSA	Yes

10. **Substantial Equivalence Conclusion**

Substantial Equivalent Table	MicrO2 OSA Device	Somnomed MAS RXA
Intended Use		
Intended as an intraoral device	YES	YES
Intended to be worn during sleep only	YES	YES
Intended to reduce snoring or help alleviate snoring	YES	YES
Intended to reduce or help alleviate mild to moderate obstructive sleep apnea	YES	YES
For single patient, multi-use	YES	YES
For personal use at home or in sleep laboratories	YES	YES
For adult patient populations	YES	YES
Prescription device	YES	YES
Cleaned daily	YES	YES
Design		
Separate upper & lower tray pieces	YES	YES
All rigid tray pieces for more stable fit	YES	YES
Patient Specific	YES	YES

Advances the lower jaw	YES	YES
Advancement position maintained by ramp design	YES	YES
Can be adjusted, repaired and/or refit	YES	YES
Ease of insertion	YES	YES
Ease of removal	YES	YES
Allows the patient to open & close mouth during wear	YES	YES
Permits patient to breathe through the mouth	YES	YES
Material		
Hard PMMA material	YES	YES
Ability to be manufactured from alternate materials based on patient needs	YES	YES
Non-sterile	YES	YES

In summary, Indications for Use, patient population, Use environment and the performance data between the MICRODENTAL, Inc. MicrO2 OSA device, and the predicate device listed in Item #5 above shows nearly identical data.

From a technical design perspective, both of the devices improve the flow of air through the patient's pharyngeal space during sleep by repositioning the mandible and the use of upper and lower trays. While the device mechanics are slightly different, they both advance the lower jaw forward in order to increase the pharyngeal space. The mechanism of each device allows for adjustment of the amount of advancement based on dentist prescription. The dentist prescribes the amount of advancement increments according the physician professional assessment in the same way that the dentist adjusts the mandibular position with the pistons, screws, straps or repositioning elastics of the predicate devices.

Both devices use primarily the same material – PMMA – to provide a rigid tray.

There are no new questions of safety or efficacy raised by the MicrO2 OSA device; therefore, the device supports a claim of Substantial Equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 24, 2014

MICRODENTAL, Inc.
Ms. Laura Sheppard
Senior Director, Compliance and Regulatory Affairs
5601 Arnold Rd
Dublin, CA 94568

Re: K133683
Trade/Device Name: MicrO2 Obstructive Sleep Apnea Device
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: June 20, 2014
Received: June 24, 2014

Dear Ms. Sheppard:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Mary S. Brimer -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 Indications for Use

Indications for Use

510(k) Number (if known): To be assigned K133683

Device Name: MicrO2 OSA Device

Indications for Use:

The MICRODENTAL, Inc. Micr02 device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Prescription Use __YES__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _NO__ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Michael E. Adjodha -S
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