DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 7, 2016

Microdental, Inc.
David Kuhns, PhD
Senior Director of Product Development And Technical Sales
5601 Arnold Rd.
Dublin, California 94568

Re: K161624
Trade/Device Name: MicrO2 OSA Device with Micro-Recorder
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: PLC
Dated: August 9, 2016
Received: August 9, 2016

Dear Dr. Kuhns:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

**510(k) Number :** K161624

**Device Name:** MicrO2 OSA Device with Micro-recorder

**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.

Optionally, if the DentiTrac® micro-recorder is completely embedded in the MicrO2 device, the micro-recorder is intended to measure patient compliance to oral device/appliance therapy in combination with the DentiTrac® System

| | | |
|---|---|---|
| Prescription Use __**YES**__<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _**NO**__<br>(21 CFR 801 Subpart C) |

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# 3 510(k) Summary

1. **Date Summary Prepared:** **October 10, 2016**

**Submitter Information:** MICRODENTAL, Inc.
5601 Arnold Rd
Dublin, CA 94568

**Contact Person:** David Kuhns, PhD
Senior Director of Product Development and Technical Sales

**2. Device Name:**

**Proprietary/Trade name:** MicrO2 OSA Device with Micro-recorder
**Common name:** Mandibular Advancement Device
**Classification name:** Intraoral devices for snoring and sleep apnea and obstructive sleep apnea
**Device Classification:** II
**Regulation number:** 21 CFR 872.5570

**Product code** **PLC**

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

**Primary Predicate:**
Device Name: SomnoDent with Micro-Recorder
Manufacturer: SomnoMed, Ltd.
510(k) Number: K150369

**Reference Predicate:**
Device Name: Micr02 OSA Device
Manufacturer: MicroDental Laboratories, Inc.
510(k) Number: K133683

**4. Device Description:**

The MicrO2 OSA device series consists of maxillary and mandibular devices that when interfaced together reduce snoring and mild to moderate sleep apnea by holding the mandible forward during sleep, providing increased pharyngeal space. 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 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 with Micro-recorder is identical to the primary predicate device, Somnomed with Micro-Recorder except for the difference in the adjustment mechanism. The MicrO2 uses twin mated posts to adjust whereas the Somnomed uses embedded screws. Without the compliance chip the subject device is identical in materials and manufacturing to the reference predicate MicrO2 OSA device. Any differences introduced by these modifications when compared to the predicate device, do not introduce any new concerns.

This submission adds the option for any clinician to decide to incorporate a DentiTrac® Micro-recorder compliance chip embedded into a MicrO2 OSA device to record a patient's compliance to the prescribed oral appliance therapy. The MicrO2 OSA device with Micro-recorder is to be used in combination with the DentTrac® System which includes a base station at the provider's office used to upload the data from the chip to a web application for cloud based reporting and tracking. During scheduled visits, the data within the DentiTrac® can be uploaded to a web application for cloud-based reporting and tracking using a DentiTrac® Base Station at the clinician's office. The DentiTrac® micro-recorder monitors the wear time through the oral temperature, as well as tracks movements and head position. This is the identical chip that is included in the predicate device – the Somnodent with Micro-Recorder. The inclusion of the embedded DentiTrac® micro-recorder, provides additional information when used in combination with the DentiTrac® System, but does not impact the operating principles of the Micr02 OSA device as established by the reference device, the MicrO2 OSA without the DentiTrac® Micro-recorder.

**5. 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.

Optionally, if the DentiTrac® micro-recorder is completely embedded into the MicrO2 appliance, the micro-recorder is intended to measure patient compliance to the oral appliance therapy in combination with the DentiTrac® System.

The Indications for Use Statement for the MicroDental, Inc. MicrO2 device with Micro-recorder is identical to the Somnodent with Micro-Recorder with the exception of the name. Both the subject and predicate devices have the same intended use for the treatment of OSA by mandibular repositioning.

**6. Comparison of Technological Characteristics with the Predicate Device**

Mandibular repositioning is the technological principle for both the subject and predicate devices. It is based on the movement of the mandible to increase the pharyngeal space. At a high level, the subject and predicate devices are based on the following elements:

- A mandible tray
- An tray on the upper jaw
- Use of a protrusion mechanism for the mandible
- Optional use of the compliance chip to monitor patient compliance with the therapy
- Material composition - PMMA

The following technological differences exist between the subject and predicate devices:

- The protrusion mechanism in the subject device is by use of a fin that is a part of the lower tray
- The digital milling process

From a technical design perspective, the subject device and the predicate 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 between the subject device and the Somnomed with Micro-Recorder, they both advance the lower jaw forward in order to increase the pharyngeal space. The Somnomed with Micro-Recorder uses screws to advance the lower tray whereas the MicrO2 with Micro-recorder and the MicrO2 reference device both use a twin mated post for advancement.

The mechanism of the subject device and the predicate devices allows for adjustment of the amount of advancement based on dentist prescription and are patient specific. The dentist prescribes the amount of advancement increments for the trays of the MicroO2 with Micro-recorder subject device and the MicrO2 OSA reference device according the physician professional assessment. The dentist prescribes these increments in the same way that the dentist adjusts the mandibular position with the pistons, screws, straps or repositioning elastics of the Somnomed with Micro-Recorder predicate device.

The MicrO2 OSA with Micro-recorder subject devices and both predicate devices use primarily the same material – PMMA – to provide a rigid tray.

The MicrO2 OSA with Micro-recorder is digitally milled identically to the MicrO2 reference device whereas the Somnomed with Micro-Recorder is manually manufactured.

Both the MicrO2 OSA with Micro-recorder and the SomnoMed with Micro-Recorder have an additional pocket to encase the Microrecorder. They both follow the same pocket process to include the DentiTrac® micro-recorder chip into the base device. The MicrO2 reference device does not have this pocket for the Microrecorder, thus the subject device – the MicrO2 OSA with Micro-recorder compliance chip is wider to include the pocket and the chip.

7. **Performance Testing:**

**Non-clinical Testing**

Risk assessment, biocompatibility assessment in accordance with ISO 10993-1 and process validation for manufacturing was generated by MicroDental Laboratories to ensure that the MicrO2 OSA devices can be repeatedly and reliably embedded with the DentiTrac® and retain the same Quality Control functionality of the MicrO2 and DentiTrac®.

MicroDental Laboratories has generated process validation for the manufacturing process. Throughout the manufacturing process, MicroDental Laboratories performs 100% visual and functional inspection to ensure that the device meets manufacturing specifications for the MicrO2 OSA device with the inclusion of the DentiTrac® MicroRecorder Compliance Chip.

There are no new materials that have been added to the subject device from the reference predicate. As such, the biocompatibility assessment that was performed for the reference predicate MicrO2 OSA device is supportive of the subject device.

**Clinical Data**

Clinical testing was not conducted on the subject device

**8. Substantial Equivalence**

MICRODENTAL, Inc. has chosen the traditional 510(k) route of submission for marketing clearance of the Micr02 OSA Device.

**Method of Action and Physical Characteristics:** SomnoDent with Micro-Recorder cleared by K150369.

| Substantial Equivalent Table | MicrO2 OSA Device with Micro-recorder **K161624** | Primary Predicate: SomnoDent with Micro-Recorder K150369 | Reference Predicate: MicrO2 OSA Device K133683 |
|---|---|---|---|
| **Intended Use** | | | |
| **Intended as an intraoral device** | YES | YES | YES |
| **Intended to be worn during sleep only** | YES | YES | YES |
| **Intended to reduce snoring or help alleviate snoring** | YES | YES | YES |
| **Intended to reduce or help alleviate mild to moderate sleep apnea** | YES | YES | YES |
| **For single patient, multi-use** | YES | YES | YES |
| **For personal use at home or in sleep laboratories** | YES | YES | YES |
| **For adult patient populations** | YES | YES | YES |
| **Prescription device** | YES | YES | YES |
| **Cleaned daily** | YES | YES | YES |

| | | | |
|---|---|---|---|
| **Option to monitor patient compliance** | YES | YES | NO |
| **Design** | | | |
| **Separate upper & lower tray pieces** | YES | YES | YES |
| **All rigid tray pieces for more stable fit** | YES | YES | YES |
| **Custom fit, unique per patient** | YES | YES | YES |
| **Advances the lower jaw** | YES | YES | YES |
| **Advancement position maintained by ramp design** | YES | YES | YES |
| **Can be adjusted, repaired and/or refit** | YES | YES | YES |
| **Ease of insertion** | YES | YES | YES |
| **Ease of removal** | YES | YES | YES |
| **Allows the patient to open & close mouth during wear** | YES | YES | YES |
| **Permits patient to breathe through the mouth** | YES | YES | YES |
| **Material** | | | |
| **Hard PMMA material** | YES | YES | YES |
| **Non-sterile** | YES | YES | YES |
| **DentiTrac® Micro-recorder embedded into MicrO2** | **YES** | **YES** | **NO** |

**Substantial Equivalence Based on Mode of Action**

The Micr02 OSA device with Micro-recorder has the same intended use as the Somnomed with Micro-Recorder in terms of providing increased pharyngeal space through mandibular repositioning for the relief of snoring and nighttime mild to moderate sleep apnea. The MicrO2 OSA and the predicate devices are both classified as mandibular positioning devices that are designed to increase the pharyngeal space. The subject device and the primary predicate maintain the option of embedding the DentiTrac® Micro-recorder compliance chip that monitors patient compliance with the device. Without the compliance chip the subject device is identical in mode of action to the reference predicate MicrO2 OSA device.

**Substantial Equivalence Based on Bench Testing**

The choice of reference predicate device, MicrO2 OSA is made from currently marketed devices which have identical intended use, and, which provide equivalent physical parameters, in terms of vertical shear, horizontal shear, horizontal compression and leachability.

The added compliance chip does not negatively impact the base the design and does not invalidate the original performance testing as performance testing as performed in support of clearance of the reference predicate device MicrO2 OSA

Both the Micr02 OSA device with the Micro-recorder as well as the Somnomed and MicrO2 predicates are prescribed and fitted by dentists or physicians. All of the devices have a mechanical/physical mode of action; the materials used for the fabrication of the subject device are identical to the materials used for the subject device.

Compression and shear testing to approximate the mechanical force applied during use of the device was performed on the reference predicate. Since the addition of the DentiTrac® Micro-Recorder compliance chip does not impact the structural integrity of the device, this testing is still applicable to demonstrate performance and support substantial equivalence.

Monomer leachability testing was performed on the reference predicate. The materials in the subject device have been changed, thus the leachability testing continues to support biocompatibility and substantial equivalence to the reference predicate.

**Substantial Equivalence with the Addition of the DentiTrac® Micro-recorder Compliance Chip**

The addition of the DentiTrac® Micro-Recorder to the MicrO2 device does not change the intended use of the MicrO2 device for the treatment of night time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years of age or older. Based on the process of embedding the DentiTrac® Micro-recorder inside the MicrO2 device, the patient will not be physically exposed to the micro-recorder. The DentiTrac® is completely sealed under a layer of PMMA within the MicrO2 device in the identical fashion as the SomnoDent with Micro-recorder has embedded the DentiTrac®. Furthermore, the size, position and location of the embedded DentiTrac® Micro-recorder in the MicrO2 device as there is ample space in the patient's oral cavity to accommodate the additional volume.

## 9. Conclusion

Based on the comparison technologic characteristics and the indications for use, together with the non-clinical performance testing,

MicrO2 Obstructive Sleep Apnea Device with Micro-recorder is substantially equivalent to the predicate devices SomnoDent with Micro-Recorder and Micr02 OSA Device.