DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 10, 2016

Airway Management, Inc.
c/o Paul Dryden
Consultant
3418 Midcourt Road, Ste. 114
Carrollton, Texas 75006

Re: K160239
Trade/Device Name: TAP® 1 & TAP® 3
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: June 29, 2016
Received: June 30, 2016

Dear Mr. Paul Dryden:

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" (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 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.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
TAP 1 and TAP 3

Indications for Use *(Describe)*
The TAP(r) family of intra-oral appliances are intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea in patients 18 years or age or older.

The DentiTrac(r) micro-recorder is completely embedded into the TAP(r) intra-oral appliance, the micro-recorder is intended to measure patient compliance to oral device / appliance therapy when used in combination with the DentiTrac(r) System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

2-Aug-16

Company	Airway Management, Inc. 3418 Midcourt Road, Ste. 114 Carrollton, TX 75006 Tel – 866-264-7667
Official Contact:	Dale Siebenmorgen Manager of Quality and Regulatory
Proprietary or Trade Name:	TAP® 1 and TAP® 3
Common/Usual Name:	Sleep appliances with patient monitoring
Product Code:	PLC
Class / CFR:	Class II, 21CFR 872.5570
Device:	TAP® 1 and TAP® 3
Predicate Device:	K150369 - SomnoMed SomnoDent® with micro-recorder
Reference Devices:	K062951 – Airway Management – TAP® 3 K964516 – NPB TAP® 1

Device Description:

Airway Management, Inc. has a family of intra-oral appliances known and referred to as the Thornton Appliance Positioner ("TAP®") family.

There have been a number of 510(k) clearances and the TAP® versions are all fundamentally the same. They are:

- Separate upper and lower trays
- Contain trays custom fitted to each patient
- Have a coupling mechanism (single point midline) that allows adjustment by way of incremental advancement of the mandible
- Allows the sleep specialists to titrate the advancement for optimum treatment effect
- Both Customized trays and Standard sized trays
- Mandibular advancement acts to increase the patient's pharyngeal space during sleep

Modification

This submission is to offer the option of an embedded micro-recorder, DentiTrac® which will record and track a patient's compliance to the prescribed oral appliance therapy.

The DentiTrac® can be incorporated into any of the TAP® family of intraoral appliances.

The DentiTrac® micro-recorder monitors the wear time through oral temperature, tracks movements, and head position. The DentiTrac® provided information when used with the

DentiTrac® System. During scheduled visits, the DentiTrac® data can be transferred to a cloud-based web application for reporting and tracking.

The addition of the DentiTrac® does not alter the principle of operation, technological characteristics, or safety of the TAP® family of intraoral appliances, which are the reference devices.

Indications for Use:
The TAP® family of intra-oral appliances are intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea in patients 18 years or age or older.

The DentiTrac® micro-recorder is completely embedded into the TAP® intra-oral appliance, the micro-recorder is intended to measure patient compliance to oral device / appliance therapy when used in combination with the DentiTrac® System.

Patient Population: Patients 18 years or older who snore or obstructive sleep apnea (OSA)

Environment of Use: Home, Dental and, Sleep laboratories

Table 1 – Comparison of Proposed Device vs. Primary Predicate

	Proposed TAP® Family with Micro-Recorder	**SomnoMed SomnoDent® with micro-recorder K150369**
Indications for Use	The TAP® family of intra-oral appliances are intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea in patients 18 years or age or older. The DentiTrac® micro-recorder is completely embedded into the TAP® intra-oral appliance, the micro-recorder is intended to measure patient compliance to oral device / appliance therapy when used in combination with the DentiTrac® System.	The SomnoDent® intra-oral devices are intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea in patients 18 years or age or older. Optionally, if the DentiTrac® micro-recorder is completely embedded into the SomnoDent® device, the micro-recorder is intended to measure patient compliance to oral device / appliance therapy in combination with the DentiTrac® System.
Environments of use	Home, Dental offices, Sleep laboratories	Home, Dental offices, Sleep laboratories
Patient Population	Patients 18 years and older	Adult patients 18 years and older
Contraindications	• Missing, infected or loose teeth • Temporary crowns or fillings • Temporomandibular Joint (TMJ) dysfunction	• Missing, infected or loose teeth • Temporary crowns or fillings • Temporomandibular Joint (TMJ) dysfunction
Prescription	Prescription use	Prescription use
Duration of use	Single patient, multi-use	Single patient, multi-use

	Proposed **TAP® Family with Micro-Recorder**	**SomnoMed** **SomnoDent® with micro-recorder** **K150369**
Design		
Types of trays	Standard tray or customized upper and lower trays are fitted to individuals	Standard tray or customized upper and lower trays are fitted to individuals
Method of customized fitting	Impression material or customized trays	Impression material or customized trays
Adjustable for setting the amount of protrusion	Can we adjusted for degree of protrusion by the dentist	Can we adjusted for degree of protrusion by the dentist
Method for holding lower jaw forward	Lower mandible is held in an advanced position by an adjustable hook or post	Lower mandible is held in an advanced position by an adjustable hook or post
Cleaning method	Cleaned by simple rinsing with water	Cleaned by simple rinsing with water
Method that DentiTrac® is attached to tray	Embedded	Embedded

Note that proposed TAP® Family with micro-recorder is identical to the reference devices cleared under K964516 (TAP® 1) and K062951 (TAP® 3) as far as the design, performance, and safety of the oral appliance without the micro-recorder.

Table 2 is a comparison of the proposed device with modification, micro-recorder, and the reference TAP® devices.

Table 2 – Comparison of Proposed Device vs. and Reference TAP® devices

	Proposed **TAP® Family with Micro-Recorder**	**Reference Devices** **K964516 (TAP® 1)** **K062951 (TAP® 3)**
Product Classification	PLC - sleep appliances with patient monitoring Cleared under LRK – device, anti-snoring Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	 LRK – device, anti-snoring Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
CFR	872.5570	872.5570

	Proposed **TAP® Family with Micro-Recorder**	**Reference Devices** **K964516 (TAP® 1)** **K062951 (TAP® 3)**
Attributes		
Indications for Use	The TAP® family of intra-oral appliances are intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea in patients 18 years or age or older. The DentiTrac® micro-recorder is completely embedded into the TAP® intra-oral appliance, the micro-recorder is intended to measure patient compliance to oral device / appliance therapy when used in combination with the DentiTrac® System.	An intra-oral appliance intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea in patients 18 years or age or older
Environments of use	Home, Dental offices, Sleep laboratories	Home, Dental offices, Sleep laboratories
Patient Population	Patients 18 years and older	Adult patients 18 years and older
Contraindications	• Missing, infected or loose teeth • Temporary crowns or fillings • Temporomandibular Joint (TMJ) dysfunction	• Missing, infected or loose teeth • Temporary crowns or fillings • Temporomandibular Joint (TMJ) dysfunction
Prescription	Prescription use	Prescription use
Duration of use	Single patient, multi-use	Single patient, multi-use
Design		
Types of trays	Standard tray or customized upper and lower trays are fitted to individuals	Standard tray or customized upper and lower trays are fitted to individuals
Method of customized fitting	Impression material or customized trays	Impression material or customized trays
Adjustable for setting the amount of protrusion	Can we adjusted for degree of protrusion by the dentist	Can we adjusted for degree of protrusion by the dentist
Method for holding lower jaw forward	Lower mandible is held in an advanced position by an adjustable hook or post	Lower mandible is held in an advanced position by an adjustable hook or post
Cleaning method	Cleaned by simple rinsing with water	Cleaned by simple rinsing with water
Method that DentiTrac® is attached to tray	Embedded	No DentiTrac®

As can be seen the Airway Management TAP® intra-oral appliances with micro-recorder are substantially equivalent to the predicate device SomnoMed, SomnoDent® with micro-recorder (K150369) for the embedded micro-recorder and identical in design as an intraoral appliance to the reference TAP® devices – K964516 – TAP® 1 and K062951 – TAP® 3.

The TAP® with micro-recorder is viewed as substantially equivalent to the predicate and reference devices because:

Indications –
Similar to predicate – K150369 – SomnoMed SomnoDent® with micro-recorder and K062951 – Airway Management TAP® 3 and K964516 – NPB TAP® 1 – Indicated to reduce or alleviate night time snoring and treat mild to moderate obstructive sleep apnea (OSA).

Technology –
Identical to predicate – K150369 – SomnoMed SomnoDent® with micro-recorder and the reference - K062951 – Airway Management TAP® 3 and K964516 – NPB TAP® 1 – both devices use a separate tray design with a means to adjust the lower jaw. Each is filed with an impression material to assure a tight fit for the user. Both incorporate the embedded DentiTrac® micro-recorder.

Materials –
The materials in contact with the patient are identical to the references K062951 – Airway Management TAP® 3 and K964516 – NPB TAP® 1.

Environment of Use –
Identical to predicate – K150369 – SomnoMed SomnoDent® with micro-recorder and K062951 – Airway Management TAP® 3 and K964516 – NPB TAP® 1.

Patient Population –
Identical to predicate – K150369 – SomnoMed SomnoDent® with micro-recorder and the references K062951 – Airway Management TAP® 3 and K964516 – NPB TAP® 1 – 18 years and older.

Performance Testing
The modification is the addition of the DentiTrac® micro-recorder which has been cleared under K150369 and data is available under MAF2557.

Embedding the device does not alter the performance of the TAP® device as an intra-oral appliance; therefore no additional performance testing is required.

Substantial Equivalence Conclusion

As detailed above, the indications for use, patient population, environment of use, technology or principle of operation, and performance are substantially equivalent to the predicate and reference devices.

Based upon the comparison to the predicate we can conclude that there are no new safety or effectiveness concerns and thus can determine then to be substantially equivalent.