September 11, 2025

Airway Technologies d/b/a Airway Management
% Paul Dryden
President
ProMedic, LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K252374
Trade/Device Name: Nylon flexTAP(R)
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: LRK
Dated: July 30, 2025
Received: August 29, 2025

Dear 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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252374

Please provide the device trade name(s).

Nylon flexTAP(R)

Please provide your Indications for Use below.

The Nylon flexTAP is intended to reduce or alleviate nighttime snoring and mild to moderate obstructive sleep apnea, OSA for adults, 18 years of age and older.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

Date Prepared:	10-Sep-258-Sept-2025
Submitter:	Airway Management 4300 Alpha Road #115 Farmers Branch, TX 75244 Tel - (469) 893-1340
Submitter Contact:	Charles Collins, CEO
Submission Correspondent:	Paul Dryden, ProMedic, LLC
Proprietary or Trade Name:	Nylon flexTAP®
Common / Usual Name:	Device, anti-snoring, Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Classification CFR:	21 CFR 872.5570
Product Code:	LRK - Device, Anti-Snoring
Predicate Device:	Airway Management – TAP T – K061732
Reference Device:	Airway Management - TOA – K972061
Reference Device:	Airway Management – myTAP 2 - K181482
Reference Device:	Panthera Dental, Inc – The Panthera Anti-Snoring Device - K143244
Classification CFR:	21 CFR 872.5570
Product Code:	LRK - Device, Anti-Snoring

Device Description:

The Nylon flexTAP is a custom-fit oral device intended to reduce or alleviate nighttime snoring and mild to moderate obstructive sleep apnea (OSA). The Nylon flexTAP device consists of 3 components:

1. Upper Tray that fits on the upper teeth
2. Lower Tray that fits on the lower teeth.
3. An Adjustment Mechanism attached to the lower tray that fits into an Adjustment Post on the upper tray.

Device Modifications:

Airway Management has previously submitted and received clearance for its custom-fit oral appliances. For this submission, we detail the design modifications outlined in this Special 510(k) premarket notification and how these modifications do not affect the intended use or the indications for use or alter the fundamental principle of operation for the device. The modifications made include changes to:

- Material Modification: The subject device includes digitally printed medical grade nylon material for the upper and lower tray.
- Titration Mechanism: The subject device utilizes an adjustment ‘dial’; whereas the predicate device utilized an adjustment ‘key’. The adjustment ‘dial’ mechanism is identical to the reference device.

The table below details the comparison between the subject device, predicate and reference devices.

Table 1 – Substantial Equivalence Table				
Attribute	**Subject Device: Nylon flexTAP**	**Predicate Device: TAP-T (K061732)**	**Reference Device: TOA (K972061)**	**Discussion**
Review Panel	Dental	Dental	Dental	Same
Device Classification	Class II	Class II	Class II	Same
Regulation	21 CFR872.5570 - Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	21 CFR872.5570 - Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	21 CFR872.5570 - Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	Same
Product Code:	LRK (Class 2) - Device, Anti-Snoring	LRK (Class 2) - Device, Anti-Snoring	LRK (Class 2) - Device, Anti-Snoring	Same as predicate
Indications for Use	The Nylon flexTAP is intended to reduce or alleviate nighttime snoring and mild to moderate obstructive sleep apnea, OSA.	The TAP T is intended to reduce or alleviate nighttime snoring and mild to moderate obstructive sleep apnea, OSA.	The TOA is intended to reduce or alleviate nighttime snoring and obstructive sleep apnea, OSA.	Identical to the predicate
Device Description	Nylon flexTAP is comprised of: • Upper tray • Lower tray • Mechanism to attach and advance lower tray relative to upper tray)	The TAP T is comprised of: • Lower tray • Upper tray • Impression material • Mechanism to attach and advance lower tray relative to upper tray	The TOA is comprised of: • Lower tray • Upper tray • Impression material • Mechanism to attach and advance lower tray relative to upper tray	Similar – The subject device utilizes an adjustment ‘dial’; whereas the predicate device utilized an adjustment ‘key’. The subject device adjustment ‘dial’ is identical to the reference device. All TAP appliances have a single point midline advancement. This means that the device only needs to be adjusted from one point, either using an

Table 1 – Substantial Equivalence Table				
Attribute	**Subject Device: Nylon flexTAP**	**Predicate Device: TAP-T (K061732)**	**Reference Device: TOA (K972061)**	**Discussion**
				adjustment dial or a hex key. Both advancement mechanisms are identical and allow for easier titration with the appliance in the mouth.
Principle of Operation	Midline adjustment of the relative position of the trays by advancing the lower tray with adjustable screw.	Midline adjustment of the relative position of the trays by advancing the lower tray with adjustable screw.	Midline adjustment of the relative position of the trays by advancing the lower tray with adjustable screw.	Same
Environment of Use	Home and clinical settings	Home and clinical settings	Home and clinical settings	Same as predicate
Population	18 years of age and older	Adults patients 18 years and older	Adults	Same as predicate
Contraindications	This device is contraindicated for patients with loose teeth, loose dental work, dentures, or other oral conditions which would be adversely affected by wearing dental appliances. In addition, the appliance is contraindicated for patients who have central sleep apnea, have severe respiratory disorders or are under 18 years of age.	This device is contraindicated for patients with loose teeth, loose dental work, dentures, or other oral conditions which would be adversely affected by wearing dental appliances. In addition, the appliance is contraindicated for patients who have central sleep apnea, have severe respiratory disorders or are under 18 years of age.	This device is contraindicated for patients with loose teeth, loose dental work, dentures, or other oral conditions which would be adversely affected by wearing dental appliances. In addition, the appliance is contraindicated for patients who have central sleep apnea, have severe respiratory disorders or are under 18 years of age.	Same as predicate
Duration of Use	Single patient, multi-use.	Single patient, multi-use.	Single patient, multi-use	Same as predicate
Method of cleaning	Water, toothbrush	Water, mild soap, toothbrush	Water, mild soap, toothbrush	Similar
Rx	Prescription only	Prescription only	Prescription only	Same as the predicate
Non-clinical performance testing	• Functional testing for durability after multiple cleanings • Flexural strength	• Functional testing for durability after multiple cleanings • Flexural strength	• Functional testing for durability after multiple cleanings	Non-clinical testing is identical to the predicate device.

Table 1 – Substantial Equivalence Table				
Attribute	**Subject Device:** **Nylon flexTAP**	**Predicate Device:** **TAP-T (K061732)**	**Reference Device:** **TOA (K972061)**	**Discussion**
	• Force testing • Drop test	• Force testing • Drop test	• Flexural strength • Force testing • Drop test	
Biocompatibility of Materials	• Surface Contacting • Mucosal membrane, • With duration of use prolonged > 24 hours < 30 days	• Surface Contacting • Mucosal membrane, • With duration of use prolonged > 24 hours < 30 days	• Surface Contacting • Mucosal membrane, • With duration of use prolonged > 24 hours < 30 days	Biocompatibility Testing requirements are identical to the predicate. Materials are identical to the reference devices (K181482 and K143244)

Discussion of Substantial Equivalence to Predicate Device

There are no differences between the subject device, predicate device and reference device except for:

1. Material Change: We have submitted a Material Certification to support biocompatibility for the materials for the subject device with the use of reference devices.
2. Titration Mechanism: The subject device utilizes an adjustment 'dial'; whereas the predicate device utilized an adjustment 'key'. The subject device's adjustment 'dial' is identical to the reference device's titration dial adjustment mechanism. All TAP appliances have a single point midline advancement. This means that the device only needs to be adjusted from one point, either using an adjustment dial or a hex key. Both advancement mechanisms are identical and allow for easier titration with the appliance in the mouth.

These differences do not raise any new questions of safety or efficacy as compared to the predicate.

Substantial Equivalence Conclusion

The subject device is substantial equivalent to the predicate device. The Nylon flexTAP does not raise any new questions of safety or efficacy as compared to the predicate.