December 18, 2025

Park Dental Research Corp.
% Jennifer Day
Regulatory Consultant
Prime Path Medtech
1321 Upland Dr
Suite 6792
Houston, Texas 77043

Re: K252976
Trade/Device Name: Park Dental Nylon MAD
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, LQZ
Dated: September 17, 2025
Received: September 17, 2025

Dear Jennifer Day:

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
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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.	K252976

Please provide the device trade name(s).

Park Dental Nylon MAD

Please provide your Indications for Use below.

The Park Dental Nylon MAD is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

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 K252976

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92.

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Date Prepared:	9/17/25
Proprietary Name:	Park Dental Nylon MAD
Common Name	Mandibular Advancement device
Product Code:	LRK & LQZ
Classification Name:	Device, Anti-Snoring & Device, Jaw Repositioning
Device Classification:	Class II
Regulation Number:	872.5570
Regulation Description:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.
Predicate Device:	The Panthera Anti-Snoring X3 Device (K171576)
Reference Device:	airVata (K240427)

Device Description:

The Park Dental Nylon Mandibular Advancement Device (MAD) is a custom-made, removable oral appliance consisting of two intraoral trays connected by an adjustable interlocking rigid rod. It is intended for use in patients diagnosed with Obstructive Sleep Apnea (OSA) and functions by advancing the lower jaw (mandible) during sleep to increase the pharyngeal airway space. This advancement reduces airway obstruction, minimizes snoring, and promotes improved sleep quality and reduced jaw tension.

510(k) Summary K252976

Indications for Use:

The Park Dental Nylon MAD is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Comparison to Predicate Devices:

Table 1. Predicate Comparison

Specification	***Subject Device:*** *Park Dental Nylon MAD*	***Predicate Device:*** *The Panthera Anti-Snoring X3 Device*	***Reference Device:*** *airVata*	***Comparison Result***
510k	N/A	K171576	K240427	N/A
Primary Product Code	LRK	LRK	LRK	Same
Secondary Product Code	LQZ	N/A	LQZ	Same as reference
Device Class	Class II	Class II	Class II	Same
Classification	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570	Same
Rx	Rx only	Rx only	Rx only	Same
Anatomical Sites	Mouth/Dentition	Mouth/Dentition	Mouth/Dentition	Same
Target Population	Adult patients	Adult patients	Adult patients	Same
Single Use/ Reusable	Reusable	Reusable	Reusable	Same
Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same
Fixed/Removable	Removable	Removable	Removable	Same
Manufacturing Method	3D Printed	3D Printed	3D Printed	Same
MAD range	Up to 5 mm at 1 mm increments	Up to 5 mm at 1 mm increments	Up to 3 mm, increments of 1 mm	Same
Connector length range	16 mm – 26 mm	Not found	19.9 mm	Similar

Specification	***Subject Device:*** *Park Dental Nylon MAD*	***Predicate Device:*** *The Panthera Anti-Snoring X3 Device*	***Reference Device:*** *airVata*	***Comparison Result***
Vertical Opening	Up to 8 mm	Up to 6 mm	Not found	Similar to prdicate
Indication for Use	The Park Dental Nylon MAD is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The Panthera Anti-Snoring X3 Device is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The airVata™ sleep appliance is indicated to reduce snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. The airVata™ sleep appliance is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.	Same as predicate

Design	Uses computer-aided design (CAD) and computer-aided Manufacturing (CAM). Uses CAD that enables a high degree of customization according to the physician or dentist prescription. The CAM and selective laser sintering guarantee precision, accuracy and consistency for each patient. Two customized splints that fit separately over the upper and lower teeth inside the mouth. The mandible splint contains button protrusions that interface with the rods.	Uses computer-aided design (CAD) and computer-aided Manufacturing (CAM). Uses CAD that enables a high degree of customization according to the physician or dentist prescription. The CAM and selective laser sintering guarantee precision, accuracy and consistency for each patient. Two customized splints that fit separately over the upper and lower teeth inside the mouth. The mandible splint contains wing protrusions that interface with the incline blocks built into the buccal of the maxillary splint	The airVata™ sleep appliance is a mandibular advancement device. It holds the mandible in a protrusive position as determined by a trained dentist. The device consists of upper and lower splints (trays), which are additive manufactured using a biocompatible light curable resin. Connectors, made of a biocompatible synthetic polymer with injection molding technology attach the upper and lower splints to maintain the forward position of the lower jaw. The device is adjustable in 1.0 mm increments by using different lower trays supplied with the device. The connectors are attached after the upper and lower splints (trays) are manufactured.	Similar to both

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Specification	***Subject Device:*** *Park Dental Nylon MAD*	***Predicate Device:*** *The Panthera Anti-Snoring X3 Device*	***Reference Device:*** *airVata*	***Comparison Result***
Material	Made from polymers (polyamide type 12), supplied by EOS. Highly resilient and durable biocompatible polymer material	Made from polymers (polyamide type 12), supplied by EOS. Highly resilient and durable biocompatible polymer material	Methacrylate-based light cured polymer resin (additively manufactured)	Same as predicate
Principle of Operation	Adjustment of the position of the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position. Push-based mandibular repositioning device, allows for nasal and/or oral breathing	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position. Push-based mandibular repositioning device, allows for nasal and/or oral breathing	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position. Push-based mandibular repositioning device, allows for nasal and/or oral breathing	Same
Image				N/A

510(k) Summary K252976

Indications for Use:

The indication for use is identical to the predicate device.

Technological Features:

The Park Dental MAD uses the same mechanism of action as the predicate product and reference product. It is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Non-Clinical Performance Testing

Durability testing was completed on the Park Dental MADs.

Fatigue testing was completed on the Park Dental MADs.

An internal manufacturing validation was performed to test the dimensional accuracy of the manufacturing process for the Park Dental MADs.

Biocompatibility assessment testing was performed on the subject device in accordance with FDA Guidance Document, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and , ISO 10993-1 ”Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”

Clinical Performance Testing

The technological characteristics, indications for use, material, and manufacturing and processes are the same or similar to the predicate device and therefore, no clinical studies were deemed necessary to demonstrate the safety and effectiveness of the subject device.

Conclusion

Based on comparison of indications for use, user population, mechanical and technological features, the Park Dental MAD is substantially equivalent to the predicate device.