May 6, 2020

Dror Orthodesign
℅ Janice Hogan
Partner
Hogan Lovelle US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K192069
Trade/Device Name: Aerodentis System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: April 10, 2020
Received: April 10, 2020

Dear Ms. Janice Hogan:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K192069

Device Name

Aerodentis System

Indications for Use *(Describe)*

The Aerodentis System is indicated for use in movement and alignment of teeth during orthodontic treatment of malocclusion.

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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K192069

510(k) SUMMARY

Aerodentis System

Submitter

Dror Orthodesign, Inc.
7 Hartom St., Mount Hotzvim
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9777507

Phone: +972 74 700 6700
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Contact Person: Michael Nadav

Date Prepared: May 4, 2020

Name of Device:

Aerodentis System

Common or Usual Name:

Sequential Aligner

Classification Name:

872.5470 Orthodontic plastic bracket

Regulatory Class:

Class II

Product Code:

NXC

Primary Predicate:

K181739 Align Technology, Inc.'s Invisalign System

Reference Device:

K130643 Orthoaccel Technologies, Inc.'s Acceledent

Device Description:

The Aerodentis System is an orthodontic system intended to adjust the patient's teeth through movement from their initial position to the desired position as a result of pulsatile mechanical force. The device is designed to achieve orthodontic tooth movement over a period of approximately 10

hours per day (typically at night). The device is suitable for patients with full complement of permanent teeth in need of upper, lower or combined jaw treatments.

The system is composed of two primary components:

- A custom-made, latex-free, plastic dental mouthpiece. The mouthpiece is inserted and worn by the patient according to a customized treatment prescription specified by the dental practitioner.
- The Personal Treatment Controller (PTC), which provides compressed air to the mouthpiece via a polyurethane tube

Indications for Use:

The Aerodentis System is indicated for use in movement and alignment of teeth during orthodontic treatment of malocclusion.

Summary of Technological Characteristics:

	Dror Orthodesign Aerodentis System (K192069)	**Align Technology, Inc. Invisalign System (K181739)**	**Orthoaccel Technologies, Inc. Acceledent Aura (K130643)**
Indications for Use	The Aerodentis System is indicated for use in movement and alignment of permanent teeth during orthodontic treatment of malocclusion.	The Invisalign System is indicated for the orthodontic treatment of malocclusion.	AcceleDent® Aura is intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps facilitate minor anterior tooth movement.
User Population	The Aerodentis System is suitable for adults and pediatric patients with full complement of permanent teeth. It is suitable for Class 1 and 2 malocclusions, including crowding, proclination and retroclination. The following movements are supported: tipping and uprighting of anterior teeth, and rotation of incisors.	The Invisalign System is suitable for adults and pediatric patients with full complement of permanent teeth. It is suitable for Class 1 and 2 malocclusions, including crowding, proclination and retroclination. The following movements are supported: tipping and uprighting of anterior teeth and rotation of incisors.	AcceleDent® Aura is an orthodontic accessory for the treatment of tooth malocclusion. It is used as an adjunctive therapy for patients with orthodontic appliances such as braces to help facilitate tooth movement.
Components	Mouthpiece and Personalized Treatment Controller	Incremental sets of aligners	Activator, Mouthpiece and Travel Case

Principles of Operation	Inflation of the balloon within the Mouthpiece provides pressure to the malpositioned teeth to move them into the desired position over time.	Incremental set of aligners provides pressure to the malpositioned teeth to move them into the desired position over time.	Uses soft pulse technology and cyclic forces to accelerate the movement of teeth
Pressure Application	Pulsatile	Constant	Pulsatile
Daily Treatment Length	8 - 14 hr/day	24 hr/day	20 minutes per day during Orthodontic treatment
Software	Yes; used to develop a patient-specific plan and control treatment delivery.	Yes; used to develop a patient specific plan.	Not Applicable

Performance Data:

The following testing was performed to establish equivalence:

- Balloon leak and fatigue testing
- Aerodentis System force analysis
- FEA to support use life
- Biocompatibility testing per ISO 10993-3, -5 and -10
- Software validation per FDA guidance
- IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-11 testing

A single center, controlled, clinical trial was conducted comparing the investigational Aerodentis System to the Invisalign control. 28 subjects were enrolled in the investigational arm and 15 in the control. 7 subjects dropped from the study (5 from the investigational arm, and 2 from the control). Subjects were followed until the average score of the mandibular and maxillary teeth achieved a Little's Irregularity Index (LII) of 1.5 or less or until 15 months of treatment, whichever came first. Safety was assessed by recording adverse events and radiographic assessment of root resorption. Efficacy was assessed by achieving an average LII score of 1.5 or less.

There were no adverse events reported throughout the study for either treatment arm. In addition, no clinically significant root resorption was observed for either group. Thus, both devices have excellent safety profiles. All subjects that completed treatment achieved an average LII score of 1.5 or less. While the time to treatment until success was longer for the subject device, once accounting for actual hours of device use, the Aerodentis System provided statistically significantly higher rates of tooth movement. This allows the user to achieve tooth alignment while being free of all appliances during normal working hours.

Conclusion:

The Aerodentis System is substantially equivalent to the Invisalign System.