July 17, 2019

Advanced Facialdontics LLC
Scott Simonetti
President
325 Lake Ave. Unit 759
St. James, New York 11780

Re: K182820
Trade/Device Name: The POD®
Regulatory Class: Unclassified
Product Code: MQC
Subsequent Product Code: OCO
Dated: April 10, 2019
Received: April 18, 2019

Dear Scott Simonetti:

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,

Srinivas Nandkumar, Ph.D.
Acting Assistant 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)*
K182820

Device Name
The POD®

Indications for Use *(Describe)*

The POD® is for the amelioration of clenching and bruxing associated with TMD and is to be used to aid in the relief of symptoms of TMD/TMJ.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Advanced Facialdontics®

510(k) Summary

1. Owner Information

Owner's Name:	Advanced Facialdontics LLC
Owner's Address:	325 Lake Ave, Unit 759 St James, NY 11780
Telephone:	(631) 379-3902
Fax:	(631) 277-4849
Contact Person:	Dr Scott Simonetti
Email:	ssimonettidds@yahoo.com
Date Prepared:	7/15/2019

2. Device Name

Trade Name:	The POD®
Common Name:	Mouthguard, Prescription
Classification:	Unclassified, Pre-Amendment
Product Code:	MQC
Subsequent Product Code:	OCO
Review Panel:	Dental
510(k) Number:	K182820

3. Predicate Devices

Primary Predicate:	Urbanek Device (K170985)
Reference Devices:	Luco Hybrid OSA Appliance (K160477) NTI Clenching Suppression System (K981546)

4. Device Description

The POD® is a prescription only, removable dental mouthguard worn on the mandibular arch during sleep. The one-piece device is fabricated for the mandibular arch and can be customized for each patient based on the clinician prescription. The dentist obtains a dental impression, prescribes the design, and once laboratory fabricated, delivers the custom-made device at the dental office to be used in the home setting.

***Materials*:** Polymethyl methacrylate (PMMA Acrylic Resin – Orthocryl®) and medical grade stainless steel wire. Only the PMMA has body contact as the SS wire is embedded within the PMMA and does not contact the body.

Duration and type of contact: Surface device with a limited duration (<24 h) contact of the skin and of mucosal membranes.

The subject device provides a disocclusion that protects the teeth and restorations while helping to reduce symptoms of pain and headaches.

5. **Indications for Use**: The POD® is for the amelioration of clenching and bruxing associated with TMD and is to be used to aid in the relief of symptoms of TMD/TMJ.

6. **Comparison to Predicate Device**

Technological Characteristics: The predicate and the subject device have the exact same following technological characteristics:

- Principle of Operation
- Indications of Use
- Prescription Device
- Custom fabricated
- Environment of Use: Home
- Removable by patient and reusable
- Provided Non-sterile
- No external energy, software or EMR
- Medical grade stainless steel

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

- Specific Type of acrylic used
- Location the device sits within the oral cavity
- Location of disocclusion mechanism

The Indications of Use statement is identical, the intended use of the devices are the same and the fundamental scientific technology of the subject device is the same as the previously cleared predicate and reference devices as shown in Table 1. Each previously cleared device utilizes a slightly different design to perform the same intended use.

Table 1: Comparison of Subject, Predicate and Reference Devices

Device	**Subject Device** **The POD®** **K182820**	**Primary Predicate** **Urbanek Device** **K170985**	**Reference Device** **Luco Hybrid OSA Appliance** **K160477**	**Reference Device** **NTI Clenching Suppression System** **K981546**
Product Code	MQC, OCO	MQC, OCO	MQC, OCO	MQC, OCO
Indications for Use	The POD® is for the amelioration of clenching and bruxing associated with TMD and is to be used to aid in the relief of symptoms of TMD/TMJ.	The Urbanek Device is for the amelioration of clenching and bruxing associated with TMD and is to be used to aid in the relief of symptoms of TMD/TMJ.	1. A device to be used for the treatment of sleep bruxism and 2. As an aid in the treatment of associated tension/migraine type headaches in adults.	For the prevention of chronic tension and temporal mandibular joint syndrome that is caused by chronic clenching of the posterior mandibular and maxillary teeth by the temporalis muscle. The device is custom made for the individual.
Design Features	Prescription Device Custom fit	Same	Same	Same
	Intraoral Device	Same	Same	Same
	Provided Non-sterile	Same	Same	Same
	Removable by patient and reusable	Same	Same	Same
Environment of Use	Home	Same	Same	Same
Principle of Operation	Disocclusion	Disocclusion	Disocclusion	Disocclusion
Location of Device	Mandibular arch	Maxillary arch	Mandibular and Maxillary arch	Central Incisors
Disocclusion Mechanism Location	1st molar and 2nd Premolar	Canines and Incisors	1st Premolars	Central Incisors
Materials	Methyl methacrylate, medical grade stainless steel	Thermoplastic acrylic resin, medical grade stainless steel	Methyl methacrylate, chrome cobalt, medical grade stainless steel	Thermoplastic acrylic resin

7. Non-Clinical Tests Performed

Bench Testing: The submission includes test data regarding the physical properties of the subject device including flexural strength, flexural modulus, maximum stress intensity factor, fracture toughness, water sorption, water solubility, and residual monomer. The physical properties comply with the pre-defined pass/fail criteria listed in the Recognized Standard ISO 20795-2:2013 Dentistry - Base Polymers - Part 2: Orthodontic Base Polymers, without any deviations, modifications or exclusions.

Biocompatibility Testing: Biocompatibility testing was conducted in accordance with the FDA guidance document "Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process." The submission includes full test reports regarding Cytotoxicity, Sensitization, and Mucosal Irritation according to ISO 10993-5 and ISO 10993-10. The subject device meets the predetermined pass/fail criteria.

In addition, a risk analysis was performed as per ISO 14971 and found no new concerns for the subject device.

8. Clinical Tests Performed

Clinical testing has not been performed.

9. Conclusion

Based upon the comparative analysis of features, materials and design, the subject device has the same intended use, similar technological characteristics and the same mechanism of action as the predicate device. Performance data shows that the subject device meets the requirements specified in the applicable standards. It is concluded that The POD® is substantially equivalent to the previously cleared device.

.