November 1, 2019

Propel Orthodontics LLC
Bryce Way
President and CEO
394 South Abbott Avenue
Milpitas, California, 95035

Re: K183018
Trade/Device Name: VPro5
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: OYH
Dated: October 14, 2019
Received: October 15, 2019

Dear Bryce Way:

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 Nandkumar, Ph.D.
Acting 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)*
K183018

Device Name

VPro5

Indications for Use *(Describe)*

The VPro5 is intended for use by the orthodontic patient during treatment with aligners to facilitate minor anterior tooth movement.

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.

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K183018

510(k) Summary
VPro5®

Submitter Name:	Propel Orthodontics LLC
Submitter Address:	394 South Abbott Ave Milpitas, CA 95035
Contact Person:	Bryce Way
Phone Number:	408-394-5851
Fax Number:	914-560-2056
Date Prepared:	October 31, 2019
Device Trade Name:	VPro5®
Classification Name:	Orthodontic Vibratory Accessory
Product Code:	OYH
Classification:	Class II pursuant to 21 C.F.R. § 872.5470
Predicate Device:	AcceleDent® Aura (K153048)
Device Description:	The VPro5® is a rechargeable, hand-held, powered, high-frequency vibration device. The device consists of the following components: the VPro5 Oscillator, the VPro5 Mouthpiece, a charging cable, and a wall charging adapter. The oscillator and mouthpiece are coupled together prior to use. During use, the C-shaped mouth piece adapter is manually applied to the occlusal surface of the teeth. The VPro5® is to be used 5 minutes per day in a single session in conjunction with aligner orthodontic treatment. The mouthpiece is connected to the oscillator and turned on by depressing a white on-switch located on the unit. When turned on the device will slowly ramp up to full vibration frequency of 120Hz. The vibrations are applied to the occlusal surface of the teeth. The device will automatically shut off after a duration of 5 minutes. The oscillator also contains LED light notifications which indicate status of the cycle progression. The mouthpiece is to be cleaned and stored in a dry place. The USB port can also be connected to a computer to display usage data.
Indications for Use:	The VPro5® is intended for use by the orthodontic patient during treatment with aligners to facilitate minor anterior tooth movement.

Performance Data:

Non-clinical and clinical performance testing completed with the VPro5® has demonstrated that the device performs safely and as intended.

Non-Clinical Performance Testing:

The VPro5® was tested to ensure conformance with the following electrical safety and electromagnetic compatibility (EMC) standards:

- IEC 60601-1 Medical Electrical Equipment – Part 1 General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2 General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-11 (2nd Edition): 2015 Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

The VPro5® is patient-contacting. The only patient-contacting component in the VPro5® is the C-shaped mouthpiece. A biocompatibility risk assessment was conducted for all components of the device per the FDA Guidance Document for Use of ISO 10993-1. Results of biocompatibility testing demonstrate that the VPro5® is biocompatible for use as intended. Cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), and intracutaneous irritation (ISO 10993-5) biocompatibility testing was conducted on the final finished device.

Software documentation of moderate level of concern was provided per the FDA Guidance Document for the "Content of Premarket Submissions for Software Contained in Medical Devices."

Bench testing conducted on 40 units of the VPro5® demonstrated that all the devices tested met criteria by being within the product specifications including evaluation of the ramp-up, vibratory frequency, acceleration, and time functionality of the device.

A two-year shelf life validation study was conducted to evaluate the performance and integrity of real time 2-year shelf-life of the mouthpiece and vibration device including through mechanical wear and exposure to artificial saliva to simulate the usage environment in the patient mouth.

Clinical Performance Testing:

Two clinical studies were performed using the VPro5®, one prospective, pivotal clinical trial and one retrospective study examining the effect of high-frequency vibration on root resorption. The two clinical studies are summarized in **Tables 1A and 1B,** below:

Table 1A.

Effect of VPro5 Therapy on Clear Aligner Tracking: A Prospective Randomized Controlled Clinical Trial

Study Design	Randomized, controlled multicenter, prospective
Arms	• Control: Subjects received clear aligners only and progressed to the next aligner every 14 days • 7-Day Sham: Subjects received a sham device and progressed to the next aligner every 7 days • 7-Day VPro5: Subjects received the VPro5 and progressed to the next aligner every 7 days • 5-Day Sham: Subjects received a sham device and progressed to the next aligner every 5 days • 5-Day VPro5: Subjects received a VPro5 and progressed to the next aligner every 5 days
Inclusion Criteria	• Subjects must be 18-45 years of age • Subject is willing and able to comply with all study procedures and sign informed consent/HIPAA forms • Subject must have complete adult dentition (excluding third molars) • Subjects must have class I malocclusion or mild class II/III malocclusions • Subject is at least one month into aligner treatment • Subject has history of and currently healthy oral hygiene (PD is <4 mm, GI<1, PI=1)
Exclusion Criteria	• Subjects who have received periodontal treatment in the previous 6 months • Subjects who are taking medication that could affect the level of inflammation, such as chronic antibiotics, phenytoin, cyclosporin, anti-inflammatory drugs, systemic corticosteroids, or calcium channel blockers • Subjects with severe class II or class III malocclusion • Subjects with skeletal class I but extreme dental malocclusion • Severe crowding that requires extraction • Subjects with more than 4 mm positive overjet or more than 2 mm negative overjet • Subjects with extreme deep bite (more than 90%) • Subjects with severe open bite (more than 2 mm) • Pregnant women • Subjects with any systemic diseases affecting bone metabolism • Smoking

	• Subjects with active, untreated caries • Subjects that require interproximal reduction or attachments during the study period
Number of Subjects	63
Mean Age (years)	29
Primary Outcome Measure	• Rate of tooth movement (mm/week) • Total tooth movement (percent tracking)
Study Duration	20-56 days (depending on study arm)
Results	Subjects in the 7-Day VPro5 and 5-Day VPro5 arms achieved a statistically significant faster rate of tooth movement compared to subjects in the Control arm. In addition, subjects in the 5-Day VPro5 arm achieved statistically significantly greater tracking (i.e., percentage of prescribed study tooth movement achieved) as compared to subjects in the 7-Day Sham arm. Both VPro5 arms had tracking comparable to the Control arm. (The 5-Day Sham arm was discontinued due to inadequate tracking and subject discomfort.) No serious device related adverse events were observed. No differences were seen in VPro5 performance between male and female subjects or based upon age. Appropriate statistical adjustments were made for the use of multiple comparisons.

Table 1B.

Effect of the Application of High-Frequency Mechanical Vibration on Tooth Length Concurrent with Orthodontic Treatment Using Clear Aligners: A Retrospective Study

Study Design	Retrospective, controlled, multicenter
Arms	• VPro5 • Control (no vibration device or sham)
Inclusion Criteria	• Class I malocclusion • Good oral hygiene, • Complete permanent dentition except for third molars • Initial anterior crowding ranging from 3 to 5 mm
Exclusion Criteria	• External apical root shortening observed at the preoperative radiographic examination • Proposed treatment included extraction of premolars and dental stripping
Number of Subjects	30
Mean Age (years)	26
Primary Outcome Measure	• Root resorption measured by tooth length

Study Duration	12 months or completion of treatment, whichever was shorter
Results	The control group showed a statistically significant decrease in tooth lengths compared to the VPro5 group, which showed change of tooth lengths that was not statistically significant.

These studies demonstrate that the VPro5® is substantially equivalent to the predicate device for use by the orthodontic patient during treatment with aligners to facilitate minor anterior tooth movement.

Substantial Equivalence:

The VPro5® is substantially equivalent to AcceleDent® Aura, cleared under K153048.

Table 2 below provides a comparison of the characteristics of the proposed device and legally marketed predicate device.

Table 2. Comparison of Proposed VPro5® Device and Predicate Device

Specification	VPro5® (TBD)	AcceleDent® Aura (K153048)	Comparison
Intended Use	Facilitation of minor anterior tooth movement during orthodontic treatment with aligners.	Facilitation of minor anterior tooth movement during orthodontic treatment with brackets and wires or aligners.	**Similar.** The predicate device is intended for use with brackets and wires or aligners, and the proposed device is intended for use only with aligners.
Indications for Use	The VPro5® is intended for use by the orthodontic patient during treatment with aligners to facilitate minor anterior tooth movement.	AcceleDent® Aura is intended for use during orthodontic treatment. It is used in conjunction with brackets and wires or aligners and helps facilitate minor anterior tooth movement.	**Similar.** The predicate device is intended for use with brackets and wires or aligners, and the proposed device is intended for use only with aligners.
Classification Regulation	21 C.F.R. § 872.5470	21 C.F.R. § 872.5470	**Same.**
Product Code	OYH	OYH	**Same.**
Device Class	II	II	**Same.**
Duration of Use	5 minutes per day during orthodontic treatment	20 minutes per day during orthodontic treatment	**Different.** The proposed device has a shorter duration of use than the predicate device.
Technological Characteristics	• Intraoral appliance • Integrated, rechargeable battery • Vibration mechanism of action	• Intraoral appliance • Integrated, rechargeable battery • Vibration mechanism of action	**Same.**
Vibration Frequency	High frequency (120 Hz)	Low frequency (30 Hz)	**Different.** The proposed device operates at a higher vibration frequency than the predicate device. The substantial equivalence of high frequency vibration for facilitating tooth movement is supported by the clinical data included in this submission.

Specification	VPro5® (TBD)	AcceleDent® Aura (K153048)	Comparison
Components	• Mouthpiece • Battery-powered oscillator • Charging cable (USB) • Wall charging adapter	• Mouthpiece • Battery-powered oscillator • Charging cable (USB) • Wall charging adapter	**Same.**
Power Source	Rechargeable battery	Rechargeable battery	**Same.**
Sterilization	• Not supplied sterile • Intended to be rinsed with water after use	• Not supplied sterile • Intended to be rinsed with water after use	**Same.**
Rx Only?	• Yes	• Yes	**Same.**

The VPro5® has similar intended use and indications for use as the previously cleared AcceleDent® Aura, use by the orthodontic patient during treatment to facilitate minor anterior tooth movement. The AcceleDent® Aura is intended for use with aligners or brackets and wires, and the VPro5® is intended for use with aligners only. In addition, the VPro5® has similar technological characteristics and principles of operation as its predicate. Although there are technological differences between the VPro5® and its predicate device, these differences do not raise different questions of safety or efficacy as confirmed by the company's testing and validation activities described in this submission.

As demonstrated by the clinical testing, summarized above, the VPro5® is substantially equivalent for facilitating minor anterior tooth movement as the predicate device. The pivotal clinical study demonstrates that the VPro5® is substantially equivalent to the predicate and that the VPro5® does not raise different questions of safety or effectiveness.