DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 8, 2016

Mr. Zaffer Syed
Senior Director, Clinical Development & Strategic Marketing
OrthoAccel Technologies Inc.
6575 West Loop South, Suite 200
Bellaire, Texas 77401

Re: K153048
Trade/Device Name: AcceleDent® Aura
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: II
Product Code: OYH
Dated: May 27, 2016
Received: June 1, 2016

Dear Mr. Syed:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): Not Assigned

Device Name: AcceleDent® Aura

Indication For Use:

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.

Prescription Use ____X_____ (21 CFR Part 801 Subpart D) AND/OR Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Device Evaluation (ODE)

_____
Division Sign-Off

510(k)_____

510(k) Summary

Modified AcceleDent® Aura

October 16, 2015

This summary of 510(k) substantial equivalence determination is being submitted in accordance with the requirements of 21 CFR part 807.92.

510(k) Submitter: OrthoAccel® Technologies, Inc.
6575 West Loop South, Suite 200
Bellaire, TX 77401
Phone: 832-803-0339
Fax: 713-583-9972

Contact: Zaffer Syed

Device trade name:	**AcceleDent® Aura**
Common name:	Orthodontic plastic bracket
Classification name:	Orthodontic plastic bracket
Regulation number:	21 CFR 872.5470
Classification:	Class II
Panel:	Dental
Product codes:	OYH
Product code names	Orthodontic vibratory accessory
Predicate Device:	AcceleDent® Aura, 510(k) Number K130643
Secondary Predicate Device:	OrthoPulse™, 510(k) Number K143120

Indications for Use:
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.

Device Description:
The AcceleDent® Aura is an orthodontic accessory for the treatment of tooth malocclusion. AcceleDent® Aura should be used by patients for twenty minutes per day in conjunction with standard orthodontic treatment.

This Premarket Notification (510(k)) is being submitted because OrthoAccel Technologies, Inc., is making labeling changes that affect the indications for use of our legally marketed AcceleDent® Aura (K130643). The technological characteristics of the device described in this 510(k) and the device described in our previous 510(k) K130643, including design, raw material, and chemical composition, and their manufacturing processes and related software, are identical.

The labeling modification includes:

I. Expansion of the indications of use to permit treatment of patients undergoing orthodontic treatment with aligners.

Thus, the modified AcceleDent® Aura with the revised indications for use includes the use of AcceleDent Aura in patients undergoing orthodontic treatment with aligners.

Indications for Use:
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.

Software:
There are no changes in the software compared to the existing AcceleDent Aura. The software design and development, software development methodology, software development process and environment are identical for the existing predicate device and the modified AcceleDent Aura.

Technological Characteristics:
There are no changes in the technological characteristics to the existing AcceleDent Aura. The device design and function are identical for the existing predicate device and the modified AcceleDent Aura.

Substantial Equivalence Information:
This Premarket Notification is being submitted solely to incorporate the addition to our indications for use for aligner to the existing AcceleDent Aura (K130643).

- There are no changes in the technological characteristics of the modified device when compared to the predicate device. The design, raw material, and chemical composition, device features as well as technical characteristics of the modified device and existing predicate device are identical.
- There are no changes in the manufacturing processes and related software required to accommodate the labeling changes.

AcceleDent Aura has the identical indications for use as the OrthoPulse™ device (K143120) and therefore the same intended use. The technological characteristics are very similar between the AcceleDent Aura and OrthoPulse; both devices are intended for home use under a prescription, and both devices are comprised of portable, battery powered devices that are placed in the user's mouth at regular intervals. Although AcceleDent Aura uses mechanical vibration to accelerate tooth movement, while the predicate OrthoPulse device uses light energy, both devices are designed to achieve the same therapeutic effect of achieving faster tooth movement.

Comparative clinical study outcomes with aligners, which are summarized in Table 5-1, demonstrate that the difference in technological characteristics compared to the predicate (K143120) does not adversely impact performance, and does not raise different questions of safety and effectiveness compared to the predicate device. A comparison of the modified AcceleDent Aura to the predicated devices is shown on Table 5-2.

Table 5-1 Comparative Clinical Outcomes with Aligners (AcceleDent Aura vs. OrthoPulse)

	AcceleDent Aura	OrthoPulse
Source	Retrospective AcceleDent Aligner Study Report (See Attachment 4)	510k Summary (K143120)
Study Design	Retrospective Cohort	Non-Randomized Crossover
Inclusion Criteria	• Males or females between and including the ages of 12 and 45 years old that had orthodontic treatment with Invisalign® • Permanent dentition with all upper and lower canine, lateral incisor and central incisor teeth present and any premolar and molar combination in the posterior of two teeth in each quadrant • Good health as determined by medical history	• Males or females between and including the ages of 12 and 70 years old scheduled for Invisalign® treatment • Permanent dentition • Mild to moderate crowding with no labiolingually displaced teeth • Class I or Class II by ½ cusp or less • Good oral hygiene
Exclusion Criteria	• Pregnancy • Smoker • Significant periodontal disease • History of use either prior to or during orthodontic treatment of any bisphosphonate medication or other medication for treatment of osteoporosis • Chronic daily use of any non-steroidal anti-inflammatory medication, estrogen, calcitonin, or corticosteroids during treatment • Any condition or use of medication which in the opinion of the investigator interferes with the biology of tooth movement	• Pregnancy • Smoker • Periodontally involved teeth • Bisphosphonate medication use during study • Spaces between anterior teeth • Enrolled in another study
Number of Subjects	97	21
% Male	35.1%	Unknown
Mean Age (Years)	28.8	34.9
Outcome Measures	• Treatment Time (Weeks) • Rate of Tooth Movement (ABO DI per Week)	• Perimeter Analysis of Mandibular Arch
Study Duration	Total time in orthodontic aligner treatment	First 6 months of orthodontic aligner treatment
Results	Statistically significantly faster rate of tooth movement ($p=0.0129$) and shorter overall treatment time ($p<0.0001$) as compared to Invisalign patients only	Statistically significantly faster tooth movement compared to baseline ($p=0.024$)

A detailed substantial equivalence table is provided below.

	Modified AcceleDent® Aura (Not assigned)	**AcceleDent® Aura (K130643)**	**OrthoPulse™ (K143120)**
Indication for Use	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.	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.	The OrthoPulse™ device 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.
Regulation Number	21 CFR 872.5470	Identical	Identical
Product Code	OYH	OYH	PLH
Device Class	II	Identical	Identical
510(k) Number	Not assigned	K130643	K143120
For use with orthodontics	Yes	Identical	Identical
Duration of Use	20 minutes per day during Orthodontic treatment	20 minutes per day during Orthodontic treatment	10 minutes per day during Orthodontic treatment
Technological Characteristics	• Intraoral appliance, similar to plastic mouth guard • Integrated, rechargeable battery • Vibration mechanism of action	• Identical • Identical • Identical	• Same • Same • LED mechanism of action
Components	• Mouthpiece • Battery-powered activator • Firmware	• Identical • Identical • Identical	• Mouthpiece with LED lights • Battery • Same
Accessories	• USB Cable • Power Adaptor • Travel Case	• Identical • Identical • Identical	• Same • Same • Carrying/charger case
Power Source	Rechargeable Battery	Identical	Same
Sterilization	• Not supplied sterile • Intended to be washed in water and/or soap daily to remove saliva	• Identical • Identical	• Same • Intended to be washed in water daily to remove saliva and cleaned with FDA cleared denture cleaning products

Conclusions:

The modified AcceleDent® Aura involves a revised indications for use that permits treatment of patients undergoing orthodontic treatment with aligners. Our modified AcceleDent Aura has the same intended use as the identified predicate devices, it has identical technology as compared to K130643 and different technology as compared to K143120. Due to the similarities in indications for use and technological characteristics associated with the modified AcceleDent Aura, the proposed device is substantially equivalent to the predicate devices (K130643, K143120).