510(k) Summary

AcceleDent® Aura

April 11, 2013

This summary of Special 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 Vibratory Accessory
Regulation number:	21 CFR 872.5470
Classification:	Class II
Panel:	Dental
Product code:	OYH
Predicate Device:	AcceleDent®, 510(k) Number K110661

Device Description:
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. AcceleDent® Aura should be used by patients for twenty minutes per day in conjunction with standard orthodontic treatment.

AcceleDent® Aura includes the Activator, Mouthpiece and Travel Case. The Activator and connected Mouthpiece are used by patients to provide a light vibration to the teeth – the Activator vibrates at a 0.25 N (25 grams) force level and 30 Hz frequency for 20 minutes when turned-on; the vibration is transmitted from the Activator through the Mouthpiece to the patient's teeth as they lightly bite down on the Mouthpiece.

The Activator and Mouthpiece assembly is light, comfortable, hands-free, and can be used while multi-tasking or while engaged in a variety of other daily activities. The Travel Case is an enclosure that may be used to

conceal, protect, and keep the AcceleDent® Aura Activator and Mouthpiece clean while not in use. The device includes a USB port, which can connect directly into a computer or power supply to recharge the battery. The USB port can also be connected to a computer to display usage data. A USB Cable and Power Adaptor are included to complete the system.

AcceleDent® Aura is a modified version of the predicate FDA-cleared AcceleDent® [(510(k) Number K110661]. The fundamental scientific technology of delivering therapeutic vibrations to teeth and the intended use have not changed with the subject AcceleDent® Aura device. A comparison table of the AcceleDent® Aura to the predicate AcceleDent® is shown below.

Comparison of AcceleDent® and AcceleDent® Aura

	AcceleDent® (Predicate Device)	AcceleDent® Aura (Subject Device)
Indication for Use	AcceleDent® is an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps facilitate minor anterior tooth movement.	AcceleDent® Aura is an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps facilitate minor anterior tooth movement.
Regulation Number	21 CFR 872.5470	21 CFR 872.5470
Product Code	OYH	OYH
Device Class	II	II
510(k) Number	K110661	K130643
For use with orthodontics	Yes	Yes
Material	Elastomer	Elastomer
Duration of Use	20 minutes per day during Orthodontic treatment	20 minutes per day during Orthodontic treatment
Power Source	Lithium Polymer Battery	Lithium Polymer Battery
Output Force	0.25 N (25 g)	0.25 N (25 g)
Frequency	30 Hz	30 Hz
Weight – Activator (grams)	65	33
Dimensions – Activator (HxLxW –mm-)	76x41x28	79x36x30
Rechargeable	Yes	Yes
Automatic Timer	Yes	Yes
Usage Data	Yes – Displayed on charging port	Yes – Displayed on PC (FastTrac Usage Report)
Activator	Yes	Yes
Mouthpiece Attachments	Same	Same
Storage	Travel Shell	Travel Case
USB Connector	No	Yes
Charging Port	Yes	No
Travel Shell	Yes	No
Travel Case	No	Yes
LED Battery Charge Indicator	Yes	Yes
Audible On/Off Switch	No	Yes
Shelf Life	2.0 years	2.0 years
Battery Life	2.5 years	2.0 years*

**Device deactivates after equivalent of 18 months of 20 minute daily sessions.*

Intended Use:
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.

Substantial Equivalence Discussion:
A thorough design control review of the modifications made in the AcceleDent® Aura has demonstrated that the device will perform safely and as intended when compared to the AcceleDent®. As a result, the AcceleDent® Aura is substantially equivalent to the predicate AcceleDent®.

Performance Testing:
Risk Analysis was performed according to ISO 14971 and the results supported implementation of the modifications. Verification testing to IEC 60601 and device specifications supplemented the analysis performed. Results of the analysis and testing showed that performance of the modifications met device specifications and further demonstrated substantial equivalence.

Clinical Testing:
No further clinical data were collected for AcceleDent® Aura.

Conclusions:
Based on the information provided in this premarket notification, it is concluded that the AcceleDent® Aura is safe and effective and is substantially equivalent to the predicate device which was the original AcceleDent®.

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

April 23, 2013

Mr. Zaffer Syed
Director, Clinical & Regulatory Affairs
OrthoAccel® Technologies, Incorporated
6575 West Loop South, Suite 200
BELLAIRE TX 77401

Re: K130643
Trade/Device Name: AcceleDent® Aura
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: OYH
Dated: March 21, 2013
Received: March 26, 2013

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,

Kwame O. Ulmer for
-S

Anthony D. Watson, B.S., M.S., M.B.A.
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~~ K130643

Device Name: AcceleDent® Aura

Indication For Use:

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.

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

Susan Runner, DDS, MA Mary S. Runner -S 2013.04.23 12:11:09 -04'00'

Division Sign-Off

510(k) K130643