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

May 26, 2017

OrthoAccel Technology Inc.
Jouana Harris-Livings
Director of Quality Assurance and Regulatory Affairs
6575 West Loop South, Suite 200
Bellaire, Texas 77401

Re: K170093
Trade/Device Name: AcceleDent® Optima
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: OYH
Dated: April 20, 2017
Received: April 21, 2017

Dear Jouana Harris-Livings:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Lori A. Wiggins -S6

for
Tina Kiang, Ph.D.
Acting 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): K170093

Device Name: AcceleDent® Optima

Indication For Use:

AcceleDent® Optima 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_____ 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)

_____
Division Sign-Off

510(k)_____

510(k) Summary - AcceleDent® Optima

K170093

January 09, 2017 (updated May 26, 2017)

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: Jouana Harris-Livings

Device trade name:	**AcceleDent® Optima**
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 and orthodontic LED accessory
Predicate Device:	AcceleDent® Aura, 510(k) Number K153048

Indications for Use:
AcceleDent® Optima 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® Optima is an orthodontic accessory for the treatment of tooth malocclusion. AcceleDent® Optima 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 the legally marketed OrthoAccel Technologies, Inc. device AcceleDent® Aura has been modified. Although the technological characteristics of the device and the indications for use described in our previous 510(k) K153048 remain unchanged, the design, raw material, manufacturing processes and related software have changed, resulting in the creation of the AcceleDent® Optima device.

Software:

The changes in software within the AcceleDent® Optima device allows for wireless transfer of data confirmed by Bluetooth and FCC testing, with a Moderate Level of Concern as determined by the risk assessment. The changes neither affect the mechanism of which the force is applied, nor the indications for use.

Material Characteristics:
Changes have been made to both the material of the activator and the mouthpiece for the AcceleDent® Optima, although they are both still Elastomers as used in the AcceleDent® Aura. Verification testing and risk evaluation has deemed these updated materials as low risk to the user.

Manufacturing Process:
There have been some changes made to the manufacturing processes in the AcceleDent® Optima device. Unlike AcceleDent® Aura, AcceleDent® Optima Activator is waterproof and thus requires ultrasonic welding to maintain the required IP rating. Additionally, assembly processes have been modified to accommodate the new design and the addition of the Charging Case. However, all major internal device components are relatively the same – PCB assembly, battery (although a NiMH rather than a lithium battery is used), and motor with off-set weight.

Performance Data Table:
The table below lists all performance testing performed on the AcceleDent® Optima to ensure its safety and efficacy.

Test	Standards/Requirements
Biocompatibility	The biocompatibility testing consisted of the following tests: Cytotoxicity, Intracutaneous Reactivity Irritation, Maximization Sensitization, and ISO/USP Acute System Toxicity. Reference ISO 10993-5:2009 (E) Reference ISO 10993-10:2010(E) Reference ISO 10993-10:2010(E)
Description	The purpose of the biocompatibility testing was to verify that the users of the AcceleDent 3G/Optima device will not experience any biological adverse reactions due to the product material, color, and manufacturing process. *AcceleDent® Optima passed Biocompatibility testing.*
Bioburden Enumeration	Since this test was conducted for study purposes only, there was no identified acceptance criteria.
Description	The bioburden testing was performed on the 3G mouthpiece and activator to determine the total number of viable microorganisms on the medical device. *AcceleDent® Optima passed Bioburden Enumeration testing.*
System Verification	This testing verified that the full system requirements, which includes the medical device hardware and optional/external mobile application and cloud server software, met the requirements serving as enhancements over Aura.

acceledent.com | info@orthoaccel.com
OrthoAccel Technologies Inc.
6575 West Loop South, Suite 200 | Bellaire, TX 77401 | 1-866-866-4919

Description	The scope of the testing is to verify that the 3G product met all of its system requirements. The system is comprised of the Activator, Charging Case, Cloud App, Mobile App, and Web Portal. *AcceleDent® Optima passed System Verification testing.*
Firmware Unit Test Verification	No standards were utilized in this testing. The design requirements for the AcceleDent® Optima firmware was tested.
Description	The purpose of this test was to verify the firmware requirement were met by firmware design. *AcceleDent® Optima passed Firmware Unit Verification testing.*
SubSystem Test Verification	This testing verified that the medical device hardware met the performance requirements of Aura for therapeutic force delivery, battery charging, usage logging, and environmental operation without the interface of optional/external software (i.e. mobile application, cloud server).
Description	The scope of this testing is to verify that the physical components of the 3G AcceleDent System function as intended. Devices under Test (DUT) are the Activator and Charging Case Assembly, AC Power Wall Adapter, Cable *AcceleDent® Optima passed SubSystem Verification testing.*
IEC 60601 3rd ed.	Each applicable requirement from IEC 60601 3rd was treated as an acceptance criterion for the product and/or documentation. The full 3G system was tested, which includes the medical device hardware and optional/external mobile application and cloud server software
Description	The scope of this testing was to perform all required medical device safety verification tests outlined in IEC 60601-1 and associated standards for 3G to ensure that it met all statutory requirements for electrical safety for medical devices sold in the US, Canada, the European Union and China. *AcceleDent® Optima passed IEC 60601 3rd ed. testing.*
IEC 62133 Battery Safety	Each requirement from IEC 62133:2012 was treated as an acceptance criterion for the battery and/or documentation.
Description	This testing was conducted on the NiMH Cell Battery (17AAAH, 17AAAH1A6Z) to verify that it met all requirements of IEC 62133:2012. The CB Scheme test procedure included the following tests: charging procedure, continuous low-rate charging, vibration, temperature cycling, incorrect installation, external short circuit, free fall, mechanical shock (crash hazard), thermal abuse, crushing of the cells, low pressure, overcharge, and forced discharge. *AcceleDent® Optima passed IEC 62133 Battery Safety testing.*
Packaging Distribution Testing	The following standards were used for testing: ASTM D 4169-14 Standard Practice for Performance Testing of Shipping Containers and Systems ASTM D 6198-12 Standard Guide for Transport Packaging Design ASTM D3951-10 Standard for Commercial Packaging
Description	The scope of this testing was to test the worse-case shipping scenario of 2 patient kit boxes shipped in an over-pack box, and a single parcel shipment of the RMA box, due to the fact that RMA boxes are not shipped in an overpack box. Two separate boxes were tested in this shipping scenario. *AcceleDent® Optima passed Packaging Distribution testing.*

acceledent.com | info@orthoaccel.com
OrthoAccel Technologies Inc.
6575 West Loop South, Suite 200 | Bellaire, TX 77401 | 1-866-866-4919

DEHP	The activator and mouthpiece could contain more than or equal to 0.1% by mass of DEHP as per design requirements.
Description	The purpose of the DEHP testing is to determine the amount of Diethylhexyl Phtalate (DEHP) present in the 3G mouthpiece and activator. *AcceleDent® Optima passed DEHP testing.*
Latex Evaluation	Test was conducted for study purposed to substantiate the claim that the device is not intentionally manufactured with latex.
Description	The purpose of the latex testing was to ensure that the 3G device will not experience any biological adverse reactions due to the presence of latex. *AcceleDent® Optima passed Latex testing.*
HFE-75 (Summative Testing)	The following standards were utilized: ANSI/AAMI HE75:2009/(R):2013 Human factors engineering – Design of medical devices ANSI/AAMI/IEC 62366:2007/(R)2013 & A1:2013 Medical Devices - Application of usability engineering to medical devices
Description	The Summative Testing was performed to demonstrate that the final AcceleDent Optima System user interface can be used by the intended users safely and effectively for the intended use and under the expected use conditions. *AcceleDent® Optima passed Summative testing.*
Bluetooth Certification	Bluetooth Radio Compliance was per Bluetooth SIG, which includes approval of BLE RF sub-system performance.
Description	The purpose of the Bluetooth Radio Compliance Testing is to test the AcceleDent 3G activator to achieve both Bluetooth SIG- BQE Certificate and Bluetooth SIG – RF Approval (Low Energy) Testing. *AcceleDent® Optima passed Bluetooth Certification testing.*
FCC Compliance Testing	The FCC compliance testing is one of the required components of the IEC 60601 testing (within the EMC testing). Refer to the IEC 60601 3rd ed. Study criteria above.
Description	Federal Communications Commission (FCC) testing is a requirement for all electronic products that radiate unintentional emissions. Receiving the FCC Mark certification certifies that the electromagnetic interference is under the limits approved by the FCC. *AcceleDent® Optima passed FCC Compliance testing.*
Physical Properties Testing for Mouthpiece	Hardness DIN ISO 7610 Density DIN EN ISO 1183-1 Tensile Strength DIN 53504/ISO 37 Elongation at Break DIN 53504/ISO 37 Tear Resistance ISO 34-1 Method B

Substantial Equivalence Information:

This Premarket Notification is being submitted to demonstrate substantial equivalence of the AcceleDent® Optima to the existing AcceleDent Aura (K153048). The data within this submission exhibits that the indications for use and the technology used to produce the

acceledent.com | info@orthoaccel.com
OrthoAccel Technologies Inc.
6575 West Loop South, Suite 200 | Bellaire, TX 77401 | 1-866-866-4919

0.25 N (25 grams) force level and 30 Hz frequency required to deliver the treatment are the same; thus, these two devices are substantially equivalent.

acceledent.com | info@orthoaccel.com

OrthoAccel Technologies Inc.
6575 West Loop South, Suite 200 | Bellaire, TX 77401 | 1-866-866-4919