DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 24, 2015

Biolux Research Ltd.
c/o Ms. Janice Hogan
Hogan Lovells US LLP
1835 Market St., 29th Floor
Philadelphia, Pennsylvania 19103

Re: K143120
Trade/Device Name: OrthoPulse™
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: PLH
Dated: July 10, 2015
Received: July 10, 2015

Dear Ms. Hogan:

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" (21 CFR 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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K143120

Device Name

OrthoPulse™

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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K143120

510(k) SUMMARY

Biolux Research Ltd.'s OrthoPulse™ Device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Biolux Research Ltd.
825 Powell Street, Suite 220
Vancouver, BC V6A 1H7
Canada

Contact Person: Kevin Strange, President and CEO

Phone: 604-669-0674
Fax: 604-608-5558

Date Prepared: July 21, 2015

Name of Device and Name/Address of Sponsor

OrthoPulse™
Biolux Research Ltd.
825 Powell Street, Suite 220
Vancouver, BC V6A 1H7
Canada

Common or Usual Name

Orthodontic LED Accessory (PLH)

Classification Name/Classification

Orthodontic plastic bracket, 21 CFR 872.5470, Class II

Predicate Devices

OrthoAccel's Acceledent (K110661, K130643)
This predicate has not been subject to a design-related recall.

Intended Use / Indications for Use

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.

Device Description

The OrthoPulse™ device is an intra-oral appliance similar to a plastic sports mouth guard that is intended for use during orthodontic treatment in conjunction with traditional orthodontic treatment with brackets and wires or aligners.

The device achieves its effect by delivering light energy to the bone, accelerating the rate of tooth movement. Light-emitting diodes ("LEDs") are embedded into the mouth-guard on a flexible circuit. Light is directed toward the alveolar surface to facilitate light treatment of the anterior arch segment during orthodontic tooth movement. The intra-oral appliance is designed to treat one arch (upper or lower), and is reversible by the patient to treat the other arch.

OrthoPulse is considered a low level light treatment device and produces light at levels 50-80 mW/cm^2 for the patient. The device is designed to comply with the lamp safety standard (IEC 62471: 2006) and with the general medical device standard IEC 60601-1 3rd Ed.

OrthoPulse includes light with wavelengths in the 850nm range (near infrared) and the treatment protocol is based on a daily treatment session of 5 minutes per arch (maxilla or mandible). The treatment time (session duration) is controlled by the software, along with the number of treatments per day.

OrthoPulse includes an integrated battery for power. The battery is rechargeable via a wireless charging platform / storage case. The device provides a wireless connection to an optional iOS application to enable monitoring of patient compliance with the treatment regimen. No other cable or connection to external devices is required.

Technological Characteristics

OrthoPulse™ has very similar technological characteristics as the predicate device. Both devices are intraoral appliances 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 OrthoPulse uses light energy to accelerate tooth movement while the predicate uses mechanical vibration, both devices are designed to achieve the same therapeutic effect of achieving faster tooth movement. The devices are both comprised of equivalent components, including the mouthpiece, battery component, and software. The differences in technological characteristics compared to the predicate do not adversely impact performance, as demonstrated in bench and clinical testing. Therefore, OrthoPulse presents similar technological characteristics as it predicate device, in support of substantial equivalence.

Performance Data

The following tests have been performed to support the substantial equivalence of OrthoPulse™:

- Optical Output Testing
- Lifetime Verification Testing
- Testing to ensure that the device can withstand bite forces in the mouth
- Testing to ensure the device can accurately detect when it is in contact with tissue
- Biocompatibility testing in accordance with ISO 10993-1, ISO 10993-5, ISO 10993-10
- Electrical safety testing in accordance with IEC 60601-1
- Electromagnetic compatibility testing per IEC 60601-1-2 (3rd ed., 2007 and CISPR 11:2010)
- Testing to validate the cleaning instructions
- Software verification and validation

Further, clinical testing of the device with orthodontic treatment demonstrated that the device may accelerate tooth movement and may decrease treatment time. Two primary clinical studies of the intra-oral OrthoPulse demonstrated device performance for its indicated use, indicating that the device may accelerate orthodontic movement of teeth and may reduce the overall treatment time for the patient when used in conjunction with traditional orthodontic treatment with brackets and wires or aligners. In a cross-over study where subjects served as their own control, 21 subjects (mean age 34.9 years) who used OrthoPulse with aligners was evaluated. Eligibility criteria included requiring that the subjects have permanent dentition, mild to moderate crowding with no labiolingually displaced teeth, Class I or Class II by ½ cusp or less, good oral hygiene, and non-smoking. Subjects who were pregnant, enrolled in another study, had periodontally involved teeth, used bisphosphonates during the study, or had spaces between anterior teeth were excluded. Perimeter measurement analysis was used to evaluate each patient's rate of tooth movement during baseline and OrthoPulse™ periods in the mandibular arch. The degree of external apical root resorption was also investigated. Study subjects were followed from the start of aligner orthodontic treatment until 6 months. Results demonstrated statistically significantly faster tooth movement compared to baseline ($p=0.024$), achieving the primary effectiveness objective of the study. There were no serious adverse events, and no root resorption, gingival recession, or pathological tooth mobility was reported throughout the study.

OrthoPulse was also evaluated in conjunction with brackets and wires in a controlled study of 33 subjects (mean age 25.0 years). Matched controls (based on subjects' age, initial crowding, eligibility criteria) were retrospectively selected before any data analysis of the OrthoPulse subjects. Eligibility criteria included requiring that the subjects have permanent dentition, moderate to severe crowding (LII ≥ 3 mm) with no labiolingually displaced teeth, Class I or Class II by ½ cusp or less, non-extraction in both arches, good oral hygiene, and non-smoking. Subjects who were pregnant, enrolled in another study, had periodontally involved teeth, used bisphosphonates during the study, or had spaces between anterior teeth were excluded. There were no differences between groups in terms of gender, ethnicity, age, and initial crowding. The rate of tooth movement was measured using the change in Little's Irregularity Index measurements in both groups to evaluate OrthoPulse™ use with fixed orthodontic appliances. Root resorption was determined by use of panoramic dental X-rays collected before treatment and after 6 months of treatment. Results demonstrated that subjects treated with OrthoPulse

showed a statistically significantly faster rate of tooth movement ($p<0.001$) compared to the control group, achieving the primary effectiveness objective of the study. There were no serious adverse events, and no gingival recession or pathological tooth mobility was reported throughout the study. Data demonstrated the absence of external apical root resorption with OrthoPulse use, and that there is no device effect of accelerated tooth movement on tooth root integrity. Therefore, results from the primary clinical studies demonstrate that subjects treated with OrthoPulse achieve statistically significantly faster rates of tooth movement than control.

Several additional clinical studies were also conducted with prototype and final OrthoPulse devices to supplement the clinical findings observed in the primary studies, and results consistently confirmed device performance for its indicated use.

Substantial Equivalence

OrthoPulse™ has the same intended use and indications for use as the predicate device. As described above, the technological characteristics are also very similar between the two devices; 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 OrthoPulse uses light energy to accelerate tooth movement while the predicate uses mechanical vibration, both devices are designed to achieve the same therapeutic effect of achieving faster tooth movement. Bench and clinical testing demonstrates that the difference in technological characteristics compared to the predicate does not adversely impact performance, and does not raise different questions of safety and effectiveness compared to the predicate device. Thus, OrthoPulse is substantially equivalent.

A detailed substantial equivalence table is provided below.

	OrthoPulse	**Acceledent (K110661, K130643)**
Intended Use	Intended for use during orthodontic treatment in conjunction with orthodontic appliances	Same
Indications for Use	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.	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.
Technological Characteristics	• Intraoral appliance, similar to plastic mouth guard • Integrated, rechargeable battery • LED mechanism of action	• Same • Same • Vibration mechanism of action
Components	• Mouthpiece with LED lights • Battery • Firmware	• Mouthpiece • Battery-powered activator • Software
Accessories	• Carrying/charging case	• Charging port • Travel shell
Power Source	Rechargeable battery	Same

	OrthoPulse	Acceledent (K110661, K130643)
Sterilization	Not supplied sterile or sterilized by the user; intended to be washed in water daily to remove saliva and cleaned with FDA-cleared denture cleaning products	Provided sterile (steam)

Conclusions

Based on the information provided in the 510(k) submission, including bench and human clinical data, OrthoPulse is substantially equivalent to the predicate device.