June 9, 2023

Biolux Technology GmbH
Daniela Penn
QMR, senior RA and CA manager
Neubaugasse 31
Absdorf, 3462
Austria

Re: K230905
Trade/Device Name: OrthoPulse 2.0E (OPi2E-100)
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PLH
Dated: May 9, 2023
Received: May 11, 2023

Dear Daniela Penn:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230905

Device Name

OrthoPulse 2.0E (OPi2E-100)

Indications for Use *(Describe)*

The OrthoPulse® device is intended to accelerate orthodontic movement of teeth which may reduce the overall treatment time for the patient. The OrthoPulse® device is intended for use during orthodontic treatment. The device is intended to be used in conjunction with traditional orthodontic treatment 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510 (k) for OrthoPulse 2.0 E

510(k) Summary
K230905

I. Submitter

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Contact Person: Daniela Penn
Email: d.penn@bioluxtec.com
Date prepared: June 08, 2023

II. Device

Name of the device:	OrthoPulse 2.0 E, Model OPi2E-100
Classification name:	Orthodontic LED Accessory (21 CFR 872.5470)
Regulatory Class:	II
Product Code:	PLH

III. Predicate Device

Name of the device:	OrthoPulse, K143120 (Primary predicate)
Classification name:	Orthodontic LED Accessory (21 CFR 872.5470)
Regulatory Class:	II
Product Code:	PLH

No reference devices were used in this submission

IV. Device Description

OrthoPulse is an intra-oral (iO), Light Emitting Diode (LED) based, phototherapy device for the stimulation of metabolic activity of the alveolar bone, and the acceleration of orthodontic tooth movement during orthodontic treatment. The device uses high-power LED arrays to produce photons at therapeutic wavelengths in the near infrared (nIR) portion of the light spectrum.
The OrthoPulse device is an intra-oral appliance 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 applicable medical device standards.
OrthoPulse includes light with wavelengths in the 850 nm 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 (firmware).

OrthoPulse includes an integrated battery for power. The battery is rechargeable via a wireless charging platform / storage case.

Radio-Frequency Transmitter
OrthoPulse contains a Bluetooth LE transmitter module that operates at 2.4 GHz. This module is active only when the device is not in use, but placed in the charging case and the 'Ready for Bluetooth' indicator is on.

Accessories:
There are currently no accessories to the device. To maintain electromagnetic compatibility (EMC) within limits, the device must be used with the cables and accessories specified by Biolux. The use of accessories or cables other than those specified or supplied may result in increased emissions or decreased immunity of the device.

V. INDICATIONS FOR USE

The OrthoPulse® device is intended to accelerate orthodontic movement of teeth which may reduce the overall treatment time for the patient. The OrthoPulse® device is intended for use during orthodontic treatment. The device is intended to be used in conjunction with traditional orthodontic treatment with brackets and wires or aligners and helps facilitate minor anterior tooth movement.

The Indications for Use statement is the same for both predicate and candidate device. The intended patient population is identical for both devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Ortho Pulse 2.0E and its predicate Ortho Pulse 1.0 intentionally share the same technological characteristics. They are made from the same materials. Use/Operation is identical. Both are battery powered (internal, rechargeable).

The OrthoPulse 2.0E device is an intra-oral, light emitting diode (LED) based device, similar to a plastic sport mouthguard, which is intended to accelerate orthodontic movement of teeth and to reduce the overall treatment time for the patient. This phototherapy device is designed to achieve its effect by delivering light energy to the alveolar bone, accelerating the rate of tooth movement. LEDs are embedded into the mouthguard 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 device is designed to treat one arch at the time (upper or lower) and is reversible for the treatment of both arches. The device is intended to be used in conjunction with traditional orthodontic appliances such as brackets and wires, or aligners.

OrthoPulse is considered a low-level light treatment device and produces light of safe levels for the patient in the 50 to 80 mW/cm2 range.

The following differences exist between the subject and predicate devices:
OrthoPulse 2.0E has a slightly larger (longer, extended) mouthpiece flange to serve a bigger patient mouth. The LED array in the expanded section is denser.
The new battery has an increased capacitance, while the output power of the device and the treatment regime remain unchanged.

OrthoPulse 2.0E has a new microcontroller to guarantee continued availability, which is based on availability of electrical components. The new microcontroller has a low-energy Bluetooth radio on board. Subsequently, the firmware in the electronic part had to be transposed to the new hardware. The new firmware has been developed based on the same requirements as the previous one. Hence, there is no difference in safety and performance of the devices.

VII. SAFETY AND PERFORMANCE DATA

In general, candidate device OrthoPulse 2.0E has been designed according to the same specifications as the predicate device, OrthoPulse 1.0 (generation 1, gen.1). Therefore, no general concerns should exist over the safety and performance of the device.

No **animal studies** are needed to evaluate the safety and performance of the device, because technical performance, materials, principles of operation are the same.

No **clinical data** are needed to evaluate the safety and performance of the device, because technical performance, materials, principles of operation are the same.

Nevertheless, as some electrical components had to be exchanged for the reason of availability, and also the international technical standards have advances since clearance of the predicate device, Biolux has executed the following strategy:

Biocompatibility testing
No biocompatibility testing was needed to evaluate the safety and performance of the device, because all patient contact material and manufacturing processes for the relevant components (mouthpiece only) are the same.

Electrical safety
As the relevant standards of the IEC 60601-series have been advanced and there are new components in the PCB-design, and the light emitting arch is slightly longer, containing more LEDs, it was decided to conduct full testing to all standards that the predicate device has been submitted to. The device complies to IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-57 standards.

Electromagnetic Compatibility (EMC)
As the standard IEC 60601-1-2 has been advanced, there are new components in the PCB-design, and the light emitting arch is slightly longer, containing more LEDs, it was decided to conduct full and complete EMC testing according to the standard IEC 60601-1-2.

Software verification and validation testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of

Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern since a failure or latent flaw in the software could not result in injury to the patient or operator. The device and the software have been specified and designed such that no condition or failure of the software could force the device to result in dangerous situations.
Software verification and validation included standard techniques such as code revied and regular testing to cover all specified states , device actions and signals (acoustic and visual).

Specific testing
The candidate device includes some functional and safety features that had not been covered through testing according to the recognized consensus standards. Therefore, Biolux has decided to provide individual testing to demonstrate the changed device continues to comply to these requirements, which had already been present and verified for the predicate device.

Battery
Since the battery capacitance has been increased, individual testing has been provided to demonstrate the specifications for duration and recharging of the device are still met. Testing demonstrated the device continues to meet its specifications. Testing was conducted with three devices and covered the two extreme conditions: run a fully powered device over the maximum treatment time and recharge a completely empty device up to 100%.
All UUT were able to demonstrate all of the items listed in the procedure and also successfully completed 2 full treatments (4 full sessions). All charge times were less than the specified maximum, and therefore fulfilled the requirement under test .

Environmental (temperature) testing
The device has several safety features which require operation of the LEDs and charging of the device only within certain temperature limits that might be reached during use, based on the environment in which the device is used. If specified or potentially critical temperatures are reached, the device is automatically stopped, LEDs powered off, until the device has reached an uncritical state again.
All specific features were tested. These included:

- mouthpiece internal temperature and shut off
- surface temperature of the Therapeutic Component mouthpiece level 1: cooldown mode
- surface temperature of the Therapeutic Component mouthpiece level 2: shut off and error
- battery charging only within specified temperature range
- internal temperature of the rigidboard
- LED array temperature level 1: Alert Threshold – cooldown mode
- LED array temperature level 2: THERM Threshold – shut off and error
- restart after cooldown mode

Testing has successfully demonstrated that the device is as safe and effective as the predicate under all thermic conditions. No device states or conditions can occur that could be hazardous for the patient or operator.

VIII. CONCLUSION

All tests have been conducted successfully. All data received during the test runs showed favorable data and supported the assumption that the device OrthoPulse 2.0E is as safe and effective as the predicate.

The non-clinical data support substantial equivalence of the device with the predicate. The hardware and software verification and validation demonstrate that the OrthoPulse 2.0E device should perform as intended in the specified use conditions. The candidate device is as safe as the predicate device that is currently marketed for the same intended use.