August 7, 2020

Diadent Group International
Kab Lee
Quality Assurance Manager
16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu
Cheongju-si, Chungcheongbuk-do 28161
Republic Of Korea

Re: K200809
Trade/Device Name: D-Lux+
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: July 15, 2020
Received: July 20, 2020

Dear Kab Lee:

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,

For Srinivas “Nandu” Nandkumar
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200809

Device Name
D-Lux+

Indications for Use *(Describe)*
The D-Lux+ is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photo-polymerized in the 385~515nm waveband of visible light.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

5.1 Application Information

Date Prepared:	August 7, 2020
Company Name and Address:	DiaDent Group International 16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea
Contact Person:	Kab Sun Lee Quality Assurance Manager Phone: +82-43-266-2315 FAX: +82-43-235-2315 Email: diadent32@diadent.co.kr

5.2 Device Information

Device Type:	Activator, Ultraviolet, For Polymerization
Regulation Description:	Ultraviolet activator for polymerization.
Review Panel:	Dental
Regulation Number:	21 CFR 872.6070
Product Code:	EBZ
Device Class:	II
510(k) Number	K200809
Device Name:	D-Lux+

5.3 Predicate Devices

The legally marketed devices to which substantial equivalence is being claimed are:

510(k) Number:	K190272 (Primary predicate)
Applicant:	Ivoclar Vivadent, AG
Device Name:	Bluephase PowerCure
Regulation Number:	21 CFR 872.6070
Product Code:	EBZ
Device Class:	II

5.4 Device Description

The subject device is packaged with the following:

D-Lux+ Handpiece
Light Probe
C-Battery
Power Cord
Instruction Manual
D-Lux+ Charger
Light Protector
Adapter
Disposable Sheaths(200ea/Box)

Name	Description
D-Lux+ Handpiece	This device turns on/off the power, sets the mode and time, and controls the operation. The handpiece includes a battery.
C-Battery	It is included in the handpiece and supplies power to the handpiece.
D-Lux+ Charger	Charge the battery when the handpiece is placed on this device.
Adapter	Supply power to the charger
Power Cord	A cord to conduct power to an adapter
Disposable sheath	Protect products and patients from contamination. Disposable, so reuse is prohibited.
Light Probe	It is connected to the handpiece so that the light emitted from the light source (LED) reaches the restoration.
Light Protector	It is inserted into the handpiece and used to protect the eyes from emitted light.
Instruction Manual	This is a document that describes information that the user needs to know, such as precautions, operating procedures, and how to use the device.

5.5 Indications For Use

The D-Lux+ is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photo-polymerized in the 385~515nm waveband of visible light.

5.6 Non-Clinical Performance Data

This device has demonstrated conformance with non-clinical performance requirements through evaluation and testing in accordance with the following harmonized standards:

- IEC 60601-1:2005+AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62471:2006 Photobiological safety of lamps and lamp systems
- IEC/EN 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 62133:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
- ISO 14971:2012 Risk management for medical devices
- FCC CFR 47:2008 Part 1. 1310 and 2.1093, Part 15. Subpart C Section 15.207 and 15.209

Additional non-clinical bench testing demonstrates the safety and effectiveness of the subject device.

5.7 Clinical Performance Data

No clinical data was collected or provided to support substantial equivalence between the subject and predicate devices.

5.8 Technological characteristics

The subject device, D-Lux+ has similar characteristics to the predicate device, Bluephase PowerCure.

First, the indications for use of the subject device and predicate device is polymerization of all light curing dental materials curing in the wavelength range of 385-515 nm.

Second, both the subject device and predicate device are these materials include restoratives, and orthodontic brackets.

	Subject Device	Primary Predicate Device	Discuss
510(k) Number	K200809	K190272	-
Product code	EBZ	EBZ	Equivalent
Device Class	II	II	Equivalent
Applicant	DiaDent Group International	Ivoclar Vivadent, AG	-
Device Name	D-Lux+	Bluephase PowerCure	-
Indications for use	The D-Lux+ is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photo-polymerized in the 385~515nm waveband of visible light.	With its "Polywave" broadband spectrum, Bluephase PowerCure is suitable for the polymerization of all light curing dental materials curing in the wavelength range of 385-515 nm. These materials include restoratives, bonding agents/adhesives, bases, liners, fissure sealants, temporaries, as well as luting materials for brackets and indirect restorations, such as ceramic inlays.	Equivalent 1) 385~515 nm wavelength 2) polymerize resinous dental materials 3) orthodontic brackets, bonding and sealing materials 4) visible light
Principles of operation	1. Disinfect contaminated surfaces of the curing light as well as light guides and anti-glare cones before each use. 2. Make sure that the stipulated light irradiance permits adequate polymerization. For that	1. Insert the Light Probe into the hand-piece Attach the Light Protector to the hand-piece. 2. Cover the Light Probe with the Disposable Sheath.	Equivalent

	purpose, check the light probe for contamination and damage, as well as the light irradiance at regular intervals. 3. Select curing program and time 4. Start: Once the selected curing time has elapsed, the curing program is automatically terminated.	3. Turn on the power and select the mode and set-up time. 4. Press the Operation button to perform light irradiation for the set time and press the button once again to stop the light irradiation. The light irradiation progress time is displayed numerically in the display window.	
Delivery form	-D-Lux+ Handpiece -D-Lux+ Charger -Light Probe -Light Protector -C-Battery (Included in the handpiece) -Adapter -Power Cord -Disposable -Sheaths(200ea/Box) -User Manual	-Charging base with power cord and power Pack -Handpiece -Handpiece support -Light guide 10>9 mm -Anti-glare shield -Anti-glare cones*3ea -Pack of sleeves (1x 50 pcs) -Instructions for Use	-
Technical Specifications – Wavelength range	385 – 515 ㎚	385 – 515 ㎚	Equivalent
Use	Prescription / Hospital	Prescription / Hospital	Equivalent
Sterility	Non-sterile	Non-sterile	Equivalent

5.9 Conclusions

1) Technological characteristics

The subject device, D-Lux+ has similar characteristics to the predicate device, Bluephase PowerCure.
1) Product Code and Regulatory Classification

: The proposed classification of the subject devices is II according to the product code, EBZ. It is the same as the predicate devices (K190272).

2) Indications for Use

: Both dental curing lights are used for light curing of dental restoratives including bonding agents/adhesives, bases, liners, fissure sealants, temporaries, as well as luting materials for brackets and indirect restorations, such as ceramic inlays.

3) Principle of Operation

: The subject device is used after inserting a Light Probe(Light Guide) and attaching a Light Protector(Anti-glare Shield). Select the appropriate mode and time and press the operation button to perform the procedure. It is the same as the predicate devices (K190272).

4) Light Source

: The subject device uses LED that produce a broadband spectrum of blue light in the wavelength range of 385-515nm. It is the same as the predicate devices (K190272).

5) Power Source

: The subject device is handpiece type using an internal rechargeable lithium ion battery. It is the same as the predicate devices(K190272).

6) Safety Test

the product has been tested to IEC60601-1 and IEC 60601-1-1-2 and meets the requirements for Electrical Safety, Including US National Deviations, and Electromagnetic compatibility. The test reports are included in this submission.

7) Biocompatibility

Direct contact with issue in not intended. Therefore ISO10993-1 is not applicable.

◯ Differences between Subject Devices and Predicates Devices

1) Operation Modes and Light Intensity

: The subject devices have several modes corresponding to the light output intensity and available times. The light output safety and performance test was conducted according to IEC 60601-1, IEC60601-1-2 and FDA guidance performance testing requirements with the difference. The testing results show that these difference do not affect safety and effectiveness .

2) Cross Infection Prevent

: The subject device uses disposable sheath and surface disinfection to prevent cross infection of the patient, which is substantially equivalent to the primary predicate device.

3) Battery Charging and Power Supply

: The subject device is wirelessly charged without a contact using a wireless charger. However, the predicate device is charged by the charging method by the contact. As a power source for the charger, the AC/DC adapter provided by the manufacturer is used. The input specifications of the adapter(100-240VAC, 50-60Hz, max 1A) are the same, but the outputs differ from each other at 6VDC/2A and 5VDC/3A respectively. These difference do not affect safety and effectiveness .

4) Light Probe

: The target device uses a light probe with an embedded LED. However, the predicate device uses a light guide. These difference do not affect safety and effectiveness .

Based on the above information and all data provided in this submission, the comparison of intended uses, technological characteristics, and non-clinical performance testing demonstrates that the subject device is substantially equivalent to the legally marketed devices identified in this submission.

D-Lux+ is an LED polymerization light, which is used for the polymerization of light-curing dental materials. This is achieved by using the same operating principle and performance criteria as for Bluephase PowerCure. Therefore, D-Lux+ is substantially equivalent to its predicate device, Bluephase PowerCure.