December 8, 2022

Foshan COXO Medical Instrument Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
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China

Re: K220826
Trade/Device Name: LED Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: September 9, 2022
Received: September 9, 2022

Dear Ray Wang:

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.
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.

510(k) Number *(if known)*

K220826

Device Name
LED Curing Light

Indications for Use *(Describe)*
For light curing polymerization of dental composites, luting materials, cements and other light cured materials.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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The assigned 510(k) Number: K220826

Tab #6 510(k) Summary

This 510(k) Summary of 510(k) substantial equivalence information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation:2022/11/22

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: LED Curing Light
Common Name: Ultraviolet activator for polymerization

Regulatory Information
Classification Name: Ultraviolet activator for polymerization
Classification: II
Product Code: EBZ
Regulation Number: 21 CFR 872.6070
Review Panel: Dental

Indication for use Statement:

For light curing polymerization of dental composites, luting materials, cements and other light cured materials.

Device Description:

The LED Curing Light is used for light curing polymerization of dental composites, luting materials, cements and other light cured materials. The device is a cordless pen style, LED light polymerization device for use by dental professionals in dental offices or dental laboratories.

The LED Curing Light protect the handpiece from gross contamination and prevent cross infection between patients by applying the single use protective sleeve. The protective sleeve (patient contact part) is made of PP material.

DB686 NANO:
The LED Curing Light DB686 NANO adopts the principle of ray radiation to solidify the light sensitive resin by shooting at it in a short time. It is composed of handpiece, cure tip, battery pack, charging base, adapter and protective sleeve. The handpiece contains the Rotary switch, Indicator light and Start key.

The LED Curing Light DB686 NANO has one mode namely: Curing light mode.

DB686 SWIFT:
The LED Curing Light DB686 SWIFT adopts the principle of ray radiation to solidify the light sensitive resin by shooting at it in a short time. It is composed of handpiece, cure tip, battery, charging base, adapter and protective sleeve. The handpiece contains the Power/Start button, Mode/ Timer button and LED Display.

The LED Curing Light DB686 SWIFT integrates three modes namely: soft up mode, high power mode and orthodontic mode.

5. Identification of Predicate Device(s)

Primary Predicate Device
510(k) Number: K200809
Product Name: D-Lux+
Manufacturer: DiaDent Group International

Reference Device:
510(k) Number: K163613
Product Name: Bluephase Style 20i
Manufacturer: Ivoclar Vivadent, AG

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- IEC 60601-1:2012 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
- IEC 80601-2-60:2019 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment;
- IEC 62471:2006 Photobiological safety of lamps and lamp systems
- IEC 62133-2 Edition1.0 2017-02 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 - Part 2: Lithium systems

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device		Predicate Device K200809	Reference Device K163613	Remark
Device name	LED Curing Light		D-Lux+	Bluephase Style 20i	/
Device model	DB686 NANO	DB686 SWIFT	D-Lux+	Bluephase Style 20i	/
Classification Regulation	21 CFR 872.6070		21 CFR 872.6070	21 CFR 872.6070	SAME
Classification	II		II	II	SAME
Product Code	EBZ		EBZ	EBZ	SAME
Common Name	Ultraviolet activator for polymerization		Ultraviolet activator for polymerization	Ultraviolet activator for polymerization	SAME
Indications for use	For light curing polymerization of dental composites, luting materials, cements and other light cured materials.		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 Style 20i 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 The proposed devices, Reference Device and the predicate device are all indicated to the polymerization of all light curing dental materials curing in the wavelength range of 385 – 515 nm.
Principles of operation	1. Clean and disinfect all the surfaces of handpiece and tip before each use. 2. Cover the Cure Tip and handpiece with the Disposable Protective Sleeve. 4. Operate the rotary switch to Cure. Press the	1. Clean and disinfect all the surfaces of handpiece and tip before each use. 2. Cover the Cure Tip and handpiece with the Disposable Protective Sleeve. 3. Select curing mode and cure times/ orthodontic	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 purpose, check the	1. Disinfect contaminated surfaces of the curing light as well as light probes and anti-glare cones before each use. 2. Make sure that the stipulated light intensity permits adequate polymerization. For that purpose, check the light probe for contamination	Different Analysis (1)

	Start key to activate light. Press once or Double press to select curing time . 5. Once the selected curing time has elapsed, the curing program is automatically terminated.	cycle(s) . 4. Short press Power/Start Button to start working. Once the selected curing time has elapsed, the curing program is automatically terminated.	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.	and damage, as well as the light intensity at regular intervals. 3. Select curing program and time 4. Start: Once the selected curing time has elapsed, the curing program is automatically terminated.	
Delivery form content	-Handpiece -Charging Base -Cure Tip -Protection glasses -Battery pack -Adapter (with Power Cord) -Protective Sleeve -User Manual	-Handpiece -Charging Base -Cure Tip -Battery (Included in the handpiece) -Adapter (with Power Cord) -Protective Sleeve -User Manual	-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 - Light probe -Anti-glare shield -Anti-glare cones -Pack of sleeves - Instructions for use	Different Analysis (2)
Wavelength range	385 – 515 nm		385 – 515 nm	385 – 515 nm	SAME
Use	Prescription / Hospital		Prescription / Hospital	Prescription / Hospital	SAME
Operational modes	1 programs: Curing light Mode:10s, 20s (1600 ~ 1800 mW/cm^2)	3 programs: - Soft up mode: 5s, 10s, 15s, 20s (1600 mW/cm^2) - High power mode: 5s (1700 mW/cm^2) - Orthodontic mode: 1-8Cycles (1800 mW/cm^2)	/	High 1,200 mW/cm^2 (10, 15, or 20 sec) Turbo 2,000 mW/cm^2 (5 Sec)	Different Analysis (3)
Power Supply	Adapter: 100V - 240V~ 50 - 60 Hz Output: 5V 1.5A Batterycharging		Adapter: 100-240VAC, 50-60Hz, Output: 6VDC/2A Wirelessly Battery charging	/	Different Analysis (4)
Sterility	Non-sterile		Non-sterile	Non-sterile	SAME
Electrical	IEC 60601-1		IEC 60601-1	IEC 60601-1	SAME

Safety	IEC 60601-1- 2	IEC 60601-1- 2	IEC 60601-1- 2	
Photobiological safety	IEC 62471	IEC 62471	/	SAME
Biocompatibility	Direct contact with issue in not intended. Therefore ISO10993-1 is not applicable.	Direct contact with issue in not intended. Therefore ISO10993-1 is not applicable.	/	SAME
Infection Control	Use disposable Protective Sleeve and surface disinfection to prevent cross infection of the Patient .	Use disposable sheath and surface disinfection to prevent cross infection of the patient.	The curing light also is sold with plastic sleeves for infection control.	Equivalent Analysis (5)

Analysis：

Analysis (1):

Although the device design and operational mode between the proposed devices and the predicate device are minor different, they are both complied with IEC60601-1, IEC 60601-1-2 and IEC 62471. The performance of proposed devices complies with IEC80601-2-60. The differences do not affect the safety and effectiveness.

Analysis (2):

The proposed devices use a Cure Tip, the predicate device uses a light guide; the proposed devices provide Protection glasses or recommend wearing Protection glasses for patients, the predicate device provide Light Protector. However, they all can block the blue light radiation outside the application part to protect the operator's eyes from blue light hazards. The performance of proposed devices complies with IEC 62471. The differences do not affect the safety and effectiveness.

Analysis (3):

The light output intensity of the proposed devices (1800 mW/cm^2) is comparable to the Reference Device (2,000 mW/cm^2) .The proposed 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. The testing results show that these difference do not affect the safety and effectiveness .

Analysis (4):

The proposed device is charged by the charging method by the contact. However, the predicate device is wirelessly charged without a contact using a wireless charger. 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) are the same, but the outputs differ from each other at 5V 1.5A and 6VDC/2A respectively. These difference do not the affect safety and effectiveness.

Analysis (5):

Both the proposed device and predicate device use disposable Protective Sleeve and surface disinfection to prevent cross infection of the patient, and the Disposable Protective Sleeves are complied with ISO 10993-5 , ISO 10993-10 and ISO 10993-11. The proposed device is substantially equivalent to the predicate device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.