



November 15, 2023

Guilin Refine Medical Instrument Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K223414

Trade/Device Name: Curing Light, Model: MaxCure 9
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: August 14, 2023
Received: August 15, 2023

Dear Kevin 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

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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

Indications for Use

510(k) Number (if known)

K223414

Device Name

Curing Light, Model: MaxCure 9

Indications for Use (Describe)

The MaxCure9 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.

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

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2023/11/9

1. Submission sponsor

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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Curing Light, Model: MaxCure 9
Model	MaxCure9
Common Name	Curing Light
Regulatory Class	Class II
Classification	21 CFR 872.6070 / Activator, Ultraviolet, For Polymerization / EBZ
Submission type	Traditional 510(K)

4. Predicate Device

1. Diadent Group International, D-Lux+ under K200809 (Primary predicate)

5. Device Description

This Curing Light is a device which generates high intensity light for polymerization of light curing materials used for dental curing purpose. This curing light is intended for use by trained dental professionals for the purpose of light curing dental resins and composites and used to restore teeth.

6. Intended use & Indication for use

The MaxCure9 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.

7. Comparison to the Predicate Device

Features	Predicate device D-Lux+	Subject device Curing Light, Model: MaxCure 9 (K223414)	Note
510(k) number	K200809	\	Same
Product code	EBZ	EBZ	Same
Intended Use & 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.	The MaxCure9 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.	Same
Principles of operation	1. Insert the Light Probe into the handpiece. Attach the Light Protector to the handpiece. 2. Cover the Light Probe with the Disposable Sheath. 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.	a) Insert the light guide into the mounting hole of the curing light. Clamp and install the light hood at the root of the light guide. b) Cover the Light Guide with the disposable isolation sleeve. c) Turn on the power and select the mode and set-up time. d) Press the mode key to perform light irradiation for the set time and press the button once again to stop the light irradiation.	Same
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)	Main unit, Charger, Light hood, Power adapter, disposable PE isolation sleeve (100ea/Box), Instruction Manual.	Same

Features	Predicate device D-Lux+	Subject device Curing Light, Model: MaxCure 9	Note
	-User Manual		
Technical Specifications – Wavelength range	385 – 515 nm	385 – 515 nm	Same
Peak wavelength	Dual peak: 405nm, 460nm	Dual peak: 400nm, 452 nm	SE, The values are similar. This difference does not raise issues of substantial equivalence.
Depth of cure	≥2mm	≥2mm	Same
Light source/Probe	a light probe with an embedded LED	a light probe with an embedded LED	Same
Operation Modes and Light Intensity	5 modes: STD (Standard) mode :900 mW/cm ² , 5, 10, 15 and 20 seconds SFT (Soft Start) mode: 1,300 mW/cm ² , 10 and 15 seconds HIG (High Power) mode: 1,300 mW/cm ² , 5, 10 and 15 seconds ORT (Orthodontic) mode:1,800 mW/cm ² , 3, 4, 5 seconds and P MAX (Max Power) mode:2,400 mW/cm ² , 1, 2 and 3 seconds	2 modes: Turbo mode: 2000 mW/cm ² , 1S, 3S Normal mode: 1000 mW/cm ² , 5S, 10S, 15S, 20S	Different 1
Cross Infection Prevent	disposable sheath	disposable PE isolation sleeve	Same
Use	Prescription / Hospital	Prescription / Hospital	Same
Sterility	Non-sterile	Non-sterile	Same
Power Source	rechargeable lithium ion battery.	rechargeable lithium ion	Same

Features	Predicate device D-Lux+	Subject device Curing Light, Model: MaxCure 9	Note
		battery.	
Battery Charging	wirelessly charged	charging method by the contact	Different 2
Power supply	100-240VAC, 50-60Hz	100V-240V AC 50Hz/60Hz	Same
outputs	6VDC/2A	DC 5V/1A	Different 2
Electrical Safety	IEC60601-1 and IEC 60601-1-1-2	IEC60601-1 and IEC 60601-1-1-2	Same
Chemical composition of patient contacting portions of the device	N/A	PE	Different 3
Biocompatibility	Direct contact with issue in not intended. Therefore ISO10993-1 is not applicable	ISO 10993-5 ISO 10993-10	Different 3

Different (1): Operation Modes and Light Intensity

The subject device has 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 differences do not affect safety and effectiveness .

Different (2): Battery Charging and Power Supply

The subject device is charged by the charging method of 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 5VDC/1A and 6VDC/2A respectively. These differences do not affect safety and effectiveness .

Different (3): Biocompatibility

Biocompatibility testing of the subject device was conducted because although the device does not come in contact with oral tissue on the chance that contact does occur. However, the predicate device is not evaluated. The testing results show that these differences do not affect safety and effectiveness.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility testing was conducted because although the device does not come in contact with oral tissue on the chance that contact does occur.

The biocompatibility evaluation for the Curing light was conducted in accordance with the FDA Guidance Section 5_510(k) Summary

for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Oral Mucosa Irritation

Software Validation

The Curing light software has been fully validated and the device software meets its Design Specifications. FDA Guidance Document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* has been followed in connection with the design of the device.

Non-clinical data

The Curing light has been tested according to the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- 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 Edition 2.0 2019-06 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
- ANSI ADA Standard No. 48-2004 (R2015) Visible Light Curing Units

Clinical data

The subject of this premarket submission, Curing light, did not require clinical studies to support substantial equivalence.

9. Conclusion

Based on the similarities in intended use, principles of operation, design rationale, test results, and performance, the subject Curing light is considered to be substantially equivalent to the predicate device.