



June 18, 2026

Guangzhou Rebornendo Medical Instrument Co., Ltd.
% Yijie You
General Manager
Qimmiq Medical Consulting Service Co., Ltd.
Rm.406, Bldg. C, Run Science Park
#18 Shenzhou Rd., Huangpu
Guangzhou, Guangdong 510663
China

Re: K253131
Trade/Device Name: Curing Light (M-Cure 6)
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: June 15, 2026
Received: June 16, 2026

Dear Yijie You:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

 Bobak
Shirmohammadi
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For Michael E. Adjodha, M.ChE., RAC, 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253131

?

Please provide the device trade name(s).

?

Curing Light (M-Cure 6)

Please provide your Indications for Use below.

?

The Curing Light (model: M-Cure 6) 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.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

K253131

510(K) Summary

1. 510(k) owner (Applicant)

Establishment Registration number:	/	
Name:	Guangzhou RebornEndo Medical Instrument Co., Ltd.	
Address:	Room 309, Building No.5, No.2, Xingye Road, Nansha District, Guangzhou City, Guangdong Province, China.	
Contact Person	Name:	Ye Cuimei
	Address:	No.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA
	TEL:	+86-15820261321
	Email:	Sales4@rebornendo.com

2. Contact Person (Authorized representative)

Name:	You Yijie
Address:	RM.406, Building C, Run Science Park, No.18 Shenzhou Road, Huangpu, Guangzhou, Guangdong 510663 P.R. China
TEL:	(+86)020-82245821
FAX:	(+86)020-82245821
Email:	jet.you@qimmiq-med.com

Date prepared: June 18, 2026

3. Device Information

Trade Name: Curing Light
Model: M-Cure 6
Classification name: Ultraviolet activator for polymerization
Review panel: Dental
Product code: EBZ
Regulation Class: II

Regulation Number: 872.6070

4. Predicate Device and reference device Information

Primary predicate device:

510(k) submitter/holder: Changzhou Sifary Medical Technology Co., Ltd.
510(K) Number: K221152
Trade Name: CuringPen Dental Curing Light
Model: CuringPen
Classification name: Activator, ultraviolet, for polymerization
Review panel: Dental
Product code: EBZ
Regulation Class: II
Regulation Number: 872.6070

Reference device:

510(k) submitter/holder: DiaDent Group International
510(K) Number: K200809
Trade Name: D-Lux+
Model: D-Lux+
Classification name: Activator, ultraviolet, for polymerization
Review panel: Dental
Product code: EBZ
Regulation Class: II
Regulation Number: 872.6070

510(k) submitter/holder: Garrison Dental Solutions, LLC
510(K) Number: K200775
Trade Name: LOOPTM LED Curing Light System
Model: CLK01
Classification name: Activator, ultraviolet, for polymerization
Review panel: Dental
Product code: EBZ
Regulation Class: II
Regulation Number: 872.6070

5. Device description

The Curing Light (model: M-Cure 6) is designed to polymerize all photo-activated dental materials in the wavelength range of 385-515 nm. It is a cordless pen-style, LED light polymerization device, and must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

The Curing Light, model: M-Cure 6, consists of main unit, light guide, light hood, bracket, and adapter. The unit is battery operated and contains an internal battery pack with Li batteries.

6. Indications for Use

The Curing Light (model: M-Cure 6) 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 predicate device

Comparison Analysis: The subject device is substantially equivalent to the predicate device, CuringPen Dental Curing Light, Model: CuringPen marketed by Changzhou Sifary Medical Technology Co., Ltd., the substantial equivalence chart is provided as follows:

Comparisons	Subject device (Curing light, model: M-Cure 6)	Predicate Device (CuringPen Dental Curing Light)	Reference device (D-Lux+)	Reference device LOOP LED Curing Light System (Model: CLK01)	Discussion of difference
510(k) Number	K253131	K221152	K200809	K200775	/
Classification	21 CFR 872.6070	21 CFR 872.6070	21 CFR 872.6070	21 CFR 872.6070	/
Product Code	EBZ	EBZ	EBZ	EBZ	/
FDA Class	Class II	Class II	Class II	Class II	/
Indication for use	The Curing Light (model: M-Cure 6) 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 CuringPen Dental Curing Light is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photo polymerized in the 380~515nm waveband of visible light. This device must	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	The LOOP is a source of illumination for curing photo-activated dental restorative materials and adhesives.	Similar, See D1

Comparisons		Subject device (Curing light, model: M-Cure 6)	Predicate Device (CuringPen Dental Curing Light)	Reference device (D-Lux+)	Reference device LOOP LED Curing Light System (Model: CLK01)	Discussion of difference
			only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in oxygen rich environment.	waveband of visible light.		
Intended User		Dentist or dental professional	Dentist or dental professional	Dentist or dental professional	Dentist or dental professional	Same
Device Design	Power source	Lithium battery:3.7V/2000mAh	3.7V DC with Lithium ion battery 5V DC with charger power	C-Battery	Litium Ion 18650 with a working voltage of 3.7 VDC	Similar, See D2

Comparisons		Subject device (Curing light, model: M-Cure 6)	Predicate Device (CuringPen Dental Curing Light)	Reference device (D-Lux+)	Reference device LOOP LED Curing Light System (Model: CLK01)	Discussion of difference
	Operational modes	Standard mode (M1, M2, M3) Fast curing mode, Soft mode, Pulse mode, Ortho mode, Caries checking mode	Standard mode RAMP mode, PULSE mode, Detect mode,	STD (Standard) mode, SFT (Soft Start) mode, HIG (High Power) mode, ORT (Orthodontic) mode, MAX (Max Power) mode	Repeat Mode Direct Restorative Mode Turbo Mode	Different, See D3
	Light source	LED light, blue and violet Wavelengths(385nm ~ 515nm)	LED light	LED light blue and violet Wavelengths(385nm ~ 515nm)	LED light, blue and violet wavelengths (390-480nm) 9.7mm light head diameter	Same, use LED light have same blue and violet Wavelengths(385nm ~ 515nm) with reference device(K200809)

Comparisons		Subject device (Curing light, model: M-Cure 6)	Predicate Device (CuringPen Dental Curing Light)	Reference device (D-Lux+)	Reference device LOOP LED Curing Light System (Model: CLK01)	Discussion of difference
	Accessories	Adapter Bracket Light hood	-Charging base -Light source head -Protective light shield -Adapter -Disposable sleeves (1x100pcs) -User Manual Optional accessories: -Light curing depth test board -Protective light glasses	-D-Lux+ Charger -Light Protector -Adapter -Power Cord -Disposable- Sheaths(200ea/Box) -User Manual	LOOP Protective Barrier Sleeves LOOP Protective Light Shield	Similar, See D4
Cross Infection Prevent		disposable isolation sleeve	Disposable sleeves	Disposable-Sheaths	disposable isolation sleeve	Similar, See D5
Composition of patient contacting Materials		disposable isolation sleeve: PE	Disposable sleeves: Not public	Disposable-Sheaths: Not public	disposable isolation sleeve: PE	Similar, See D6
Technical specification	Light Intensity	Standard mode: -1000 mW/cm ² , -1500 mW/cm ² , -2300 mW/cm ²	1) Standard mode: -2300 mW /cm ² -1500 mW/cm ² -1000 mW/cm ²	STD (Standard) mode :900 mW/cm ² SFT (Soft Start) mode: 1,300mW/cm ²	Repeat Mode: 1000, 1500 and 2000 mW/cm ^{2*} Direct Restorative Mode: 1000, 1200 and 1500 mW/cm ^{2***}	Similar, See D7

Comparisons		Subject device (Curing light, model: M-Cure 6)	Predicate Device (CuringPen Dental Curing Light)	Reference device (D-Lux+)	Reference device LOOP LED Curing Light System (Model: CLK01)	Discussion of difference
		Soft mode: 1000 mW/cm ² Pulse mode: 1000 mW/cm ² Caries checking mode: 600mW/cm ² Ortho mode: 1800 mW/cm ² Fast curing mode: 2500 mW/cm ²	2) RAMP mode: 1000 mW/cm ² 3) PULSE mode: 1000 mW/cm ² 4)Detect mode: 600 mW/cm ²	HIG (High Power) mode: 1,300 mW/cm ² ORT (Orthodontic) mode:1,800 mW/cm ² MAX (Max Power) mode:2400 mW/cm ²	Turbo Mode: 2000, 2500 and 3000 mW/cm ² ** * Relative to lens surface ** Relative to the target surface Device indicates illumination power and time selection	
	wavelength range	385nm ~ 515nm	380-515 nm	385~515nm	390~480nm	Same with reference device D- Lux+(K200809)
	Peak wavelength	Dual peak: 405nm, 460nm	Dual peak: 400-410nm, 450-460nm	405nm, 460nm	Not public	Same with reference device D- Lux+(K200809)
	Depth of cure	≥2mm	≥2mm	Not public	Not public	Same

Justifications for differences between proposed device and the predicate device are shown as below:

<p><u>D1:</u></p>	<p>The indications for use of the subject device are the same as for the predicate device CuringPen Dental Curing Light(K221152), except that the CuringPen Dental Curing Light has a wavelength range of 380-515nm per ISO 10650:2018 while the subject device(M-Cure 6), has a wavelength range of 385-515nm, but same with the reference device D-Lux+(K200809) with wavelength range of 385-515nm.</p> <p>The difference does not raise new question of safety and effectiveness.</p>
<p><u>D2:</u></p>	<p>The subject device is handpiece type using an internal rechargeable lithium ion battery, which is the same as the predicate device CuringPen Dental Curing Light(K221152). The battery power of subject device is similar with predicate device, the subject device can work normally and meet the performance including Light Intensity, Depth of cure under battery power.</p> <p>So the difference doesn't raise new questions of safety and effectiveness.</p>
<p><u>D3:</u></p>	<ol style="list-style-type: none"> 1.The subject device M-Cure 6 has same Standard mode and PULSE mode with the predicate device CuringPen Dental Curing Light(K221152). 2.The subject device has a Caries checking mode, which is functionally equivalent to the Detect mode of the predicate device CuringPen Dental Curing Light(K221152). Both are non-curing modes intended for diagnostic purposes. 3. The subject device M-Cure 6 has a Soft mode, while the predicate device has a RAMP mode. Both modes are designed to gradually increase light intensity. And M-Cure 6 has same Soft mode with the reference device D-Lux+(K200809).

	<p>4. The Fast curing mode of the subject device is functionally equivalent to the MAX (Max Power) mode of the reference device D-Lux+. Both names indicate a mode that provides high-intensity, continuous light output for rapid curing.</p> <p>5. The subject device M-Cure 6 has Ortho mode, which are same as ORT (Orthodontic) mode of the reference device D-Lux+(K200809).</p> <p>Therefore, the difference does not raise new question of safety and effectiveness.</p>
<p><u>D4:</u></p>	<p>The subject device has Adapter, Bracket, and Light hood, while the predicate device CuringPen Dental Curing Light(K221152) has Charging base, Protective light shield, Adapter, Disposable sleeves (1x100pcs), User Manual. The bracket of the subject device is used for holding the device during battery charging, Light hood of the subject device is used to protect dentists from hurting eyes, which have the same functions with charging base, protective light shield of the predicate device CuringPen Dental Curing Light respectively</p> <p>The accessories of the subject device are covered in the predicate device; therefore, the difference does not raise new question of safety and effectiveness.</p>
<p><u>D5:</u></p>	<p>The subject device uses disposable isolation sleeve to prevent cross infection of the patient, which has the same function with the predicate device CuringPen Dental Curing Light(K221152) using the disposable sleeve.</p> <p>The difference does not raise new question of safety and effectiveness.</p>
<p><u>D6:</u></p>	<p>As the subject device uses disposable isolation sleeve to prevent cross infection of the patient, the disposable isolation sleeve contacts with patient, while Disposable-Sheaths of primary devices use contacts with patient. The disposable isolation sleeve of subject device has cleared 510K.</p> <p>Therefore, the difference does not raise new question of safety and effectiveness.</p>

D7:

1. Light Intensity of the subject device M-Cure 6 for standard mode(M1, M2, M3 mode,1000, 1500, 2300mW/cm²),soft mode(1000 mW/cm²), pulse mode(1000 mW/cm²) and caries checking mode(600 mW/cm²), are same with those of the predicate device CuringPen Dental Curing Light(K221152).
2. Light Intensity of the subject device M-Cure 6 for Ortho mode(1800 mW/cm²) is same with the reference device D-Lux+(K200809).
3. Light Intensity of the subject device M-Cure 6 for Fast curing mode(2500 mW/cm²) is a little larger than MAX (Max Power) mode(2400 mW/cm²) of the reference device D-Lux+(K200809), but same with the reference device LOOP LED Curing Light System(K200775).

Therefore, the difference does not raise new question of safety and effectiveness.

8. Discussion of Non-Clinical Tests Performed for substantial equivalence are as follows

The device performed performance testing to demonstrate and support substantial equivalence when compared to the predicate and the applicable standards.

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- 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
ISO 10650: 2018	Dentistry - Powered polymerization activators
IEC 62471:2006	Photobiological safety of lamps and lamp systems
IEC 62133-2: 2017/AMD1:2021	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
IEC 62304:2006+A1:2015	Medical device software - Software life cycle processes
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation

- **Electrical Safety and Electromagnetic Compatibility Testing**

The Device was tested and complied with the applicable requirements of the following standards: ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 80601-2-60 demonstrated that the basic safety and performance of the device met the requirements.

- **Biocompatibility Testing**

According to FDA Guidance-Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and ISO 10993-1:2018, we performed the biocompatibility evaluation and test of direct-contacting mucosal membrane components:

- (1) In vitro Cytotoxicity test according to ISO 10993-5:2009
- (2) Skin Sensitization test according to ISO 10993-10:2021
- (3) Irritation test according to ISO 10993-23:2021

The test results verified the device compliance to recognized consensus standards and therefore does not raise new questions of safety and effectiveness.

- **Software Verification and Validation**

Software verification and validation was performed, and it was demonstrated that the software performs as intended according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The test results verified the device compliance to recognized consensus standards and therefore does not raise new questions of safety and effectiveness.

9. Concise summary for any performance testing

9.1 Summary of Performance testing – bench

The Curing Light (model: M-Cure 6) complies with the performance requirements established by standard ISO 10650:2018. Non-clinical tests performed to establish substantial equivalence to the identified predicate device (K221152) include irradiance over distance testing, peak wavelength testing, and depth of cure testing as suggested by the FDA Guidance Document "Dental Curing Lights – Premarket Notification [510(k)]" issued on March 27, 2006.

9.2 Performance Testing – Animal

Not applicable to this submission for the Curing Light device. The subject of this premarket submission, Curing Light device, did not require animal studies and test results to support substantial equivalence.

9.3 Performance Testing – Clinical

Not applicable to this submission for the Curing Light device. The subject of this premarket submission, Curing Light device, did not require clinical studies to support substantial equivalence.

Based on summary of non-clinical tests, the devices meet all the requirement of the standards.

10. Substantial Equivalence Conclusion

The Curing Light (model: M-Cure 6) has the same intended use and similar characteristics as the cleared predicate device CuringPen Dental Curing Light.

Moreover, The Curing Light (model: M-Cure 6) meets the safety and performance standards required for Curing Light device, as verified by the bench tests included in this submission, which demonstrate that the differences that existed between M-Cure 6 and CuringPen Dental Curing Light device do not raise any new questions of safety or effectiveness.

Thus, the Curing Light (model: M-Cure 6) is Substantially Equivalent (SE) to the predicate device.