February 13, 2020

Foshan CICADA Dental Instrument Co., Ltd.
℅ Jet Li
Regulation Manager
KEDA Biological Technology Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, CHINA

Re: K192233
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: December 7, 2019
Received: December 16, 2019

Dear Jet Li:

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 Srivinas ‘Nandu’ Nandkumar, Ph.D.
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)*
K192233

Device Name
LED Curing Light, Model CV-215

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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 872.6070.

1. Submitter Information

Sponsor: Foshan ClCADA Dental Instrument Co, Ltd .

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Contact Person: Juan Liu

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Application Correspondent: Jet Li

Company: Guangzhou KEDA Biological Technology Co., Ltd

E-mail: med-jl@foxmail.com

Phone: 86-18588874857

Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China

2. Subject Device Information

Type of 510(k) submission:	Traditional
Common Name:	Dental Curing Light Device
Trade Name:	LED Curing Light, Model CV-215
Classification Name:	Ultraviolet activator for polymerization
Review Panel:	Dental
Product Code:	EBZ
Regulation Number:	21 CFR 872.6070
Regulation Class:	2

3. Predicate Device Information

Sponsor:	DENTALL Co., Ltd.
Common Name:	Ultraviolet Activator for Polymerization
Trade Name:	Delight, Delight ortho, B&Lite S
510(k) number:	K170529
Review Panel:	Dental
Product Code:	EBZ
Regulation Number:	21 CFR 870.1130
Regulation Class:	2

4. Device Description

LED Curing Light is used to restore teeth on dental patient. The device can only be used by the dentist who is qualified and well trained. This product is used on dental patient in the place of hospital or professional medical site.

LED Curing Light adopts the principle of ray radiation to solidify the light sensitive resin by shooting at it in a short time. It is composed of high-power LED, main unit, curing light shield, charger and charge station. The main unit contains the ON/OFF button, display screen, mode button and time button.

LED Curing Light provides TURBO mode and NORMAL mode with different preset exposure time. The high-power LED can produce visible blue light in the 430nm to 490nm waveband of spectrum with a power density of 1000m W/cm^2 to 1800m W/cm^2. Using different modes gives dental professionals the flexibility to polymerize virtually almost all types of composites, boding agents and sealants available in the market.

The enclosure of main unit was composed of ABS material and Aluminum, and the light guide base (patient contact part) was made from ABS material.

5. Intended Use/ Indication for Use

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

6. Test Summary

LED Curing Light has been evaluated the safety and performance by lab bench testing according to the following standards:

- **Performance Testing**

The light output Performance of subject device was evaluated for below testing item:

☒ ANSI ADA 48: 2004 Visible light curing unit (FDA recognition number 4-139)

☒ IEC 80601-2-60 Medical Electrical Equipment - Part 2-60: Particular Requirements For The Basic Safety And Essential Performance Of Dental Equipment, Edition 1.0 2012-02 (FDA recognition number 4-229)

- ***Electrical safety and electromagnetic compatibility (EMC)***

Electrical safety and EMC testing were conducted on the subject device, and was found to comply with ANSI/AAMI 60601-1 and IEC 60601-1-2.

Detail standard lists is as below items:

- ANSI/AAMI 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2005+A1:2012 (FDA recognition number 19-4)
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests, 2014 (FDA recognition number 19-8)

- **Biocompatibility Testing**

The biocompatibility of subject device was evaluated for below items:

- ISO 10993-5:2009, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity (FDA recognition number 2-245)
- ISO 10993-10 Third Edition 2010-08-01, biological evaluation of medical devices - part 10: tests for irritation and skin sensitization (FDA recognition number 2-174)

- **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 determined to be of "moderate" level of concern.

7. Clinical Testing

Clinical data were not required in this submission to support a finding of substantial equivalence.

8. Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise any new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Verdict
Manufacturer	Foshan CICADA Dental Instrument Co, Ltd	DENTALL Co., Ltd. (K170529)	--
Product Name	LED Curing Light, Model: CV-215	Delight, Delight ortho, B&Lite S	SE Note 1
Indications for Use			
Indications for Use	For light curing polymerization of dental composites, luting materials, cements and other light cured materials.	For light curing polymerization of dental composites, luting materials, cements and other light cured materials.	SE
Device Design			
Power source	Rechargeable Lithium battery with IEC 62133 Approval	Li-ion battery with IEC 62133 Approval	SE
Light source	5W high-power blue light LED	blue light LED	SE Note 2
Operational mode	TURBO mode: exposure time (1,3 seconds) NORMAL mode: exposure time (5,10,15,25,30 seconds)	Standard: 5,10,15, 20s duration High: 3,6,9,12 s duration Soft start: 5, 10, 15s duration	SE Note 2
Usability	The Display screen and function buttons (ON/OFF, Mode, Time) located on the main unit.	A plastic rotation switch provides various modes selection. An ON/OFF button activates and executes the selected mode.	SE Note 2

Elementsof Comparison	Subject Device	Predicate Device	Verdict
Accessories	Curing light shield, Charger, Adapter, and the main unit	Cordless handpiece, Battery packs, Curing light shield	SE
Technical Specifications			
Light intensity	1000mW/cm^2-1800mW/cm^2 ±10%	800mW/cm^2-2700mW/cm^2	SE Note 3
Light wavelength	430nm-490nm	430~490nm range	SE
Peak wavelength	455 nm	460nm	SE
Material information			
Patient Contact material: Light guide base	ABS plastic (Comply with ISO 10993-5; ISO 10993-10)	ABS plastic (Comply with ISO 10993-5; ISO 10993-10)	SE
FDA-Recognized Standards			
Electrical safety, EMC, Biological Evaluation	ANSI/AAMI 60601-1:2005+A1 2012 IEC 60601-1-2:2014 IEC 80601-2-60:2012 ADA No 48:2004 ISO 10993-5:2009 ISO 10993-10:2010	IEC 60601-1 IEC 60601-1-2 ADA 48 / ISO 10650 ISO 10993-5:2009 ISO 10993-10:2010	SE

Note 1

Although there is little difference for their model name, but its common names are the same. This difference does not affect the safety and effectiveness.

Note 2

Although the device design and operational mode between the predicate device and subject device are minor different, they are both complied with IEC60601-1 and its performance comply with IEC80601-2-60, AND ADA 48. The differences do not affect the safety and effectiveness.

Note 3
Although the light output intensity specification is mirror different, but the light intensity range of subject device is within the effective power range of predicate device, and the safety and performance of the subject device is verified via tests, and it is complied with IEC 60601-1 and IEC 80601-2-60. The differences do not affect the safety and effectiveness.

9. Conclusion

The subject device LED Curing Light has all features of the predicate device for intended use. Thus, the subject device is substantially equivalent to the predicate device.

10. Summary Prepared Date

09 Jan 2020