November 23, 2022

Changzhou Sifary Medical Technology Co., Ltd.
℅ Jie Zhu
RA Specialist
Changzhou Sifary Medical Technology Co., Ltd
No. 99, Qingyang Road, Xuejia County, Xinbei District
Changzhou City, Jiangsu Province 213000
China

Re: K221152
Trade/Device Name: CuringPen Dental Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: September 23, 2022
Received: September 28, 2022

Dear Jie Zhu:

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)*
K221152

Device Name
CuringPen Dental Curing Light

Indications for Use *(Describe)*
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 only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in the oxygen-rich environment.

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.

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510(K) Summary
K221152

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2022/09/23

1. Submission Sponsor

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2. Submission Correspondent

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Contact person: Jie Zhu
E-mail: amanda@sifary.com
Tel: +86 0519-85962691

3. Subject Device

Trade/Device Name	CuringPen Dental Curing Light
Model	CuringPen
Common Name	CuringPen Dental Curing Light
Regulatory Class	Class II
Regulation	21CFR 872.6070
Classification Name	Ultraviolet activator for polymerization
Product code	EBZ
Submission type	Traditional 510(K)

4. Predicate Device

Manufacturer: DiaDent Group International

Device name: D-Lux+

510(K) Number: K200809

5. Device Description

The CuringPen Dental Curing Light is designed to polymerize all photo-activated dental materials in the wavelength range of 380-515 nm per ISO 10650:2018. 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 and not used

in the oxygen-rich environment.

6. Indications for Use

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 only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in oxygen-rich environment.

7. Comparison to the Predicate Device

Features	**Subject Device** **CuringPen Dental Curing Light**	**Predicate Device K200809** **D-Lux+**	**Comparison**
Applicant	Changzhou Sifary Medical Technology Co., Ltd.	DiaDent Group International	/
Classification Regulation	21CRF 872.6070	21CRF 872.6070	Same
Classification and Code	Class II EBZ	Class II EBZ	Same
Common name	Activator, ultraviolet for polymerization	Activator, ultraviolet for polymerization	Same
Indications for use	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 only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in oxygen-rich environment.	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.	Substantially equivalent (SE1)

Features	**Subject Device** **CuringPen Dental Curing Light**	**Predicate Device K200809** **D-Lux+**	**Comparison**
Principles of operation	Step-by-step: 1. Disinfect contaminated surfaces of the light source head, protective light shield, handpiece before each use. 2. Make sure that the stipulated light irradiance permits adequate polymerization. For that purpose, check the light source head 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.	Step-by-step: 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 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.	Same
Delivery form	-Handpiece -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+ Handpiece -D-Lux+ Charger -Light Probe -Light Protector -C-Battery (Included in the handpiece) -Adapter -Power Cord -Disposable Sheaths(200ea/Box) -User Manual	Substantially equivalent (SE2)
Power source	3.7V DC with Lithium ion battery 5V DC with charger power	3.6V DC with Lithium ion battery 6V DC with charger power	Substantially equivalent (SE3)
Light source	LED light	LED light	Same
Wavelength range	380-515 nm	385-515 nm	Substantially equivalent (see SE1)
Peak wavelength	Dual peak: 400-410nm, 450-460nm	Dual peak: 405nm, 460nm	Substantially equivalent (SE4)

Features	Subject Device CuringPen Dental Curing Light	Predicate Device K200809 D-Lux+	Comparison
Operational modes	1) Standard mode: -2300 mW /cm^2 -1500 mW/cm^2 -1000 mW/cm^2 2) RAMP mode: 1000 mW/cm^2 3) PULSE mode: 1000 mW/cm^2 4) Detect mode: 600 mW/cm^2	1) STD (Standard) mode: 900 mW/cm^2 2) SFT (Soft Start) mode: 1300 mW/cm^2 3) HIG (High Power) mode: 1300 mW/cm^2 4) ORT (Orthodontic) mode: 1800 mW/cm^2 ORT P (Pulse Mode): 1800 mW/cm^2 5) MAX (Max Power): 2400 mW/cm^2	Substantially equivalent (SE5)
Depth of cure	≥2mm	≥2mm	Same
Use	Prescription / Hospital	Prescription / Hospital	Same
Sterility	Non-sterile	Non-sterile	Same
Recognized Standards	ISO 10650:2018 IEC 80601-2-60:2019 IEC 60601-1:2005+A1:2012 IEC 60601-1-2:2014 IEC 60601-1-6:2010+A1:2013 IEC 62471:2006 ISO 14971:2019 ISO 10993-5:2009 ISO 10993-10:2010	IEC 60601-1:2005+A1:2012 IEC 60601-1-2:2014 IEC 60601-1-6:2010+A1:2013 IEC 62471:2006 IEC 62133:2017 ISO 14971:2012 FCC CFR 47:2008	Substantially equivalent (SE6)

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

SE1: The indications for use of CuringPen Dental Curing Light are the same as for the predicate device, except that the CuringPen Dental Curing Light has a wavelength range of 380-515nm per ISO 10650:2018 while the D-Lux+ has a wavelength range of 385-515nm. The CuringPen Dental Curing Light output is 5nm lower on the bottom end of the range. In both devices the lower wavelength LED is for the purpose of activating the TPO photo-initiator that some resin based composites use. TPO's absorption spectrum is 380-425nm and TPO presents a very high absorption peak located at the 380 nm region. Besides, the indications for use of CuringPen Dental Curing Light emphasize that the device must only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in oxygen-rich environment. These differences do not affect safety and effectiveness.

SE2: The handpiece (has a built-in battery), charging base, light source head, protective light shield, adapter, disposable sleeves of CuringPen Dental Curing Light have the same functions with the D-Lux+ Handpiece, D-Lux+ Charger, Light Probe, Light Protector, C-Battery (Included in the handpiece), Adapter, Power Cord and Disposable Sheaths of the D-Lux+. Both devices adopt the cordless pen-style. CuringPen Dental Curing Light has optional accessories: light curing depth test board and protective light glasses. Light curing depth test board is only used for testing and verifying the depth of cured resin during training process. Protective light glasses provide an additional solution to protect dentists from hurting eyes. These differences have no influence on safety and effectiveness.

SE3: Both devices use the internal rechargeable lithium ion battery. Though the battery technical specification of CuringPen Dental Curing Light is a bit different from that of the predicate device, the battery of CuringPen Dental Curing Light meets the IEC 62133-2 standard. This difference does not affect safety and effectiveness.

SE4: Both CuringPen Dental Curing Light and D-Lux+ have dual peak wavelength. The peak wavelength of CuringPen Dental Curing Light is described as a range, while the peak wavelength of D-Lux+ is described as given values. The values are similar. This difference does not raise issues of substantial equivalence.

SE5: The CuringPen Dental Curing Light has several modes corresponding to the light output intensity and available times. The light output safety and performance test were 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. Besides, the light intensity (mW/cm^2) of the predicate device encompass the range of the subject device; therefore we determine that this difference in modes does not raise issues of substantial equivalence.

SE6: The summary of the predicate device states that direct contact with issue in not intended. Therefore ISO10993 series standards are not applicable for D-Lux+. While CuringPen Dental Curing Light considers the accidental contact and ISO 10993 series standards apply. IEC 62133 is safety standard for battery. CuringPen Dental Curing Light uses batteries which comply with this standards and this can be seen verified in IEC 60601-1 test reports. The predicate device uses wireless charger, thus FCC CFR 47 applies, while the subject device does not use wireless charger. These differences do not raise issues of substantial equivalence.

Therefore, CuringPen Dental Curing Light is substantially equivalent to the predicate device-D-Lux+.

8. Summary of Non-clinical Data

The following non-clinical data were provided in support of the substantial equivalence determination.

Performance testing:

CuringPen Dental Curing Light complies with the performance requirements established by standard ISO 10650:2018. Non-clinical tests performed to establish substantial equivalence to the identified predicate device (K200809) include irradiance over distance testing, peak wavelength testing, depth of cure testing and heat generation testing as suggested by the FDA Guidance Document “Dental Curing Lights – Premarket Notification [510(k)]” issued on March 27, 2006.

Biocompatibility testing:

CuringPen Dental Curing Light does not come in contact with the patient oral tissue on the chance that contact does occur. The light source head of CuringPen Dental Curing Light, which is covered with the disposable sleeve, may shortly (not exceed 24 hours) contact with the patient oral mucosa unintentionally.

The biocompatibility evaluation of the CuringPen Dental Curing Light was conducted in accordance with the FDA Guidance 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 (ISO 10993-5: 2009)
- Sensitization (ISO 10993-10: 2010)
- Irritation (Oral mucosa) (ISO 10993-10: 2010)

Testing concluded that the test article did not have a cytotoxicity effect, did not elicit sensitization reactions, and did not elicit significant oral mucosa irritation reactions.

Software verification and validation testing:

Software verification and validation testing were conducted as recommended in IEC 62304:2006+A1:2015 Medical device software - Software life cycle processes and FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for the CuringPen Dental Curing Light was considered as a "moderate" level of concern based on the determination that minor injury could result prior to mitigation of hazards due to software failure.

Electrical safety and electromagnetic compatibility testing:

The product has been tested to IEC 60601-1-2:2014, IEC 80601-2-60:2019, and ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, and meets the requirements for Electrical Safety, including Electromagnetic Compatibility. The test reports are included in this submission.

9. Summary of Clinical Data

There were no clinical tests performed for the CuringPen Dental Curing Light device.

10. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.