September 16, 2022

Dentmate Technology Co. Ltd.
Cheng-Feng Chou
President
8F, No.8-11, Sec. 1, Zhongxing Road,
Wugu District,
New Taipei, 24872
Taiwan

Re: K221194
Trade/Device Name: LEDEX WL-120
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: July 11, 2022
Received: July 18, 2022

Dear Cheng-Feng Chou:

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 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)*
K221194

Device Name
LEDEX WL-120

Indications for Use *(Describe)*
LEDEX WL-120 is a visible curing unit programmed for polymerization of dental light cured materials by dental professionals.

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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K221194

510(k) Summary

Date: 04/21/2022

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Applicant/Submitter

DENTMATE TECHNOLOGY CO., LTD.
Registration Number: 3007662989
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TEL: +886 2 8976 9226 Fax: +886 2 8976 9236 Email: info@dentmate.com.tw

2. Official/Submission correspondent

Mr. Cheng-Feng Chou
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TEL: +886 2 8976 9226 Fax: +886 2 8976 9236 Email: info@dentmate.com.tw

3. Device Information

Common Name: LED Dental Curing Light
Device Trade Name: LEDEX
Model Number: WL-120
Classification name: Ultraviolet Activator for Polymerization
Device class: II
Panel: Dental
Product Code: EBZ
Regulation Number: 872.6070

4. Indications for use

LEDEX WL-120 is a visible curing unit programmed for polymerization of dental light cured materials by dental professionals.

5. Predicate device

LEDEX WL-090/WL-090+, (K)131042 by DENTMATE TECHNOLOGY CO., LTD.

6. Description of device

The LEDEX WL-120 device using highly efficient LEDs with a thermal management system, while maintaining consistent performance even in the most challenging and demanding curing needs. The light has four LED curing chips with a range of 390 nm to 480 nm, thus effectively curing all composites.

About the light guide rod, it is made of genuine optical fiber which can optimize light conduction and minimize loss of light from source to tip. It therefore ensures the most possible intensity of light at the light guide tip.

Furthermore, we design advanced efficient cooling heat sink which accompanies with over temperature protection. The thermal protection circuits prevent the light from overheating and help to keep the device in a safety mode. Automatic memorizing the last group of operation is another unique feature of this device.

7. Substantial Equivalence

LEDEX WL-120 is substantially equivalent to the predicate devices LEDEX WL-090/WL-090+ (K)131042 by DENTMATE TECHNOLOGY CO., LTD. in terms of intended use, technology and principle of operation.

The following comparison table is presented to demonstrate substantial equivalence.

Descriptive Information	Subject Device	Predicate device
Trade name and model number	LEDEX WL-120	LEDEX WL-090/WL-090+
Manufacturer	DENTMATE TECHNOLOGY CO., LTD.	DENTMATE TECHNOLOGY CO., LTD.
510(k) number	--	K131042
Product Code	EBZ	EBZ
Regulatory Class	II	II
Indications for use	LEDEX WL-120 is a visible curing unit programmed for polymerization of dental light cured materials by dental professionals.	LEDEX (Family model: WL-090, WL-090+) is a visible curing unit programmed for polymerization of dental light cured materials by dental professionals.
Device Design – Operational modes	Low, Ramp, Standard, High, Turbo, Plasma, White	Low, Ramp, Standard, High, Fast Ortho, Turbo, Plasma

Device Design – Light source	10W LED	10W LED
Device Design – Power source	3.7V Rechargeable Li-ion battery	3.7V Rechargeable Li-ion battery
Device Design – Power supply	Input: AC100~240V, 50/60Hz Output: DC 5V/2A	Input: AC100~240V, 50/60Hz Output: DC 5V/2A
Device Design – Accessories	Handpiece, Power supply, Optical fiber light guide rod, Filter, Light guide sleeves, Cradle, Anti-glare shield	Handpiece, Power supply, Optical fiber light guide rod, Filter, Light guide sleeves, Cradle, Anti-glare shield
Composition of Materials – outer casing	ABS plastic material	ABS plastic material
Technical Specifications – Light intensity	MAX. 3200 mW/cm2	MAX. 3200 mW/cm^2
Technical Specifications – Peak wavelength	405 & 460 nm	405 & 460 nm
FDA-Recognized Standards – Electrical safety	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) ISO 10650:2015 Dentistry - Powered polymerization activators	IEC 60601-1:1988, Medical Electrical Equipment - Part 1: General Requirements for Safety; including Amendment 1(1991) and Amendment 2(1995).
FDA-Recognized Standards – Electromagnetic compatibility	IEC 60601-1-2: 2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests ISO 10650:2015 Dentistry – Powered polymerization activators	IEC 60601-1-2, (Second Edition, 2001), Medical electrical equipment - Part 1-2: General requirements for safety; Electromagnetic Compatibility - Requirements and tests.

7.1 The same between subject device and predicate device:

a) Product Code, Regulatory Class and Manufacturer

b) Indications for use

c) Light source, Power supply and Accessories

d) Outer casing material

e) Light intensity and Peak wavelength

7.2 The different between subject device and predicate device:

a) Operational modes

The subject 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, ANSI/ADA specification no.42, ANSI/ADA specification no. 42-2 and FDA guidance performance testing requirements with the difference. The testing results show that these differences do not raise any problems in the safety and performance.

b) FDA-Recognized Standards – Electrical safety & Electromagnetic compatibility

The subject devices accord to new version of Electrical safety & Electromagnetic compatibility Standard; the predicate device was made in 2013, it accorded to old version of Electrical safety & Electromagnetic compatibility Standard.

8. Identification of the risk analysis method

The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA). The design verification tests that were performed as a result of this risk analysis assessment are listed as below. The test methods used are the same as those submitted in the original submission.

Descriptive Information	Test Performed	Acceptance Criteria
FDA-Recognized Standards: ANSI/ADA Standard No. 48-2-2010 (R2015)	Ask to Electromagnetic Compatibility test	Pass test and got Verification of Compliance
	Ask to Electrical Safety test	Pass test and got Verification of Compliance

9. Performance Testing

The following tests were conducted to evaluate the functionality, performance and substantial equivalence.

a) Irradiation (Optical power testing)

b) Spectral irradiance plot (Wavelength spectrum testing)

c) Depth of cure (Composite hardness testing)

The tests are in accordance with the following standards:

●American National Standard/American Dental Association (ANSI/ADA) Specification No. 48-2: 2010, Reaffirmed 2015, LED Curing Lights

●American National Standard/American Dental Association (ANSI/ADA) Specification No. 48: 2020, Approved 2020, Curing Lights (Powered Polymerization Activators)

●FDA Guidance for Industry and FDA Staff, Dental Curing Lights -Premarket Notification 510(k) Submissions, Clause 8. Performance Specifications

The test results conformed to the requirements of the standards.

10. Conclusion

Validation and verification tests have been conducted to FDA guidance document Dental Curing Lights –Premarket Notification [510(k)]. In comparing between subject device and predicate device, there are the same product code, regulatory classification, indications for use, light source, power supply, outer casing material, light intensity and peak wavelength of patient contacting portions.

In summary, the WL-120 LED Dental Curing Light in this submission are, in our opinion, substantially equivalent to the predicate device. Safety and performance testing supports substantial equivalence of the subject device to the predicate devices.