January 10, 2020

DXM Co., Ltd
% Dave Kim
President
Mtech Group
8310 Buffalo Speedway
Houston, Texas 77025

Re: K191221
Trade/Device Name: Cybird LED Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: November 29, 2019
Received: December 11, 2019

Dear Dave Kim:

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 Srinivas “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)*

K191221

Device Name
Cybird LED Curing Light
Model: Cybird WPT

Indications for Use *(Describe)*

The Cybird LED 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 400-480 nm 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.

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510(k) Summary

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

Date 510k summary prepared: December 6, 2019

I. SUBMITTER

Submitter's Name	DXM Co., Ltd.
Submitter's Address	Baekseok-dong, Ilsan technotown 1003, 138, Ilsan-ro, Ilsandong-gu Goyang-si, Gyeonggi-do, Republic of Korea 411-360
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II. DEVICE

Trade/proprietary Name	Cybird LED Curing Light
Model:	Cybird WPT
Common or Usual Name	Dental Curing Light Device
Regulation Name	Ultraviolet Activator for Polymerization
Regulation Number	21 CFR 872.6070
Product Code	EBZ
Regulatory Class	Class II
Review panel	Dental

III. PREDICATE DEVICE

Primary Manufacturer	DXM Co., Ltd
Trade/proprietary Name	Cybird LED Curing Light
Model:	Cybird GOLD / Cybird XD
510K Number	K173876
Common or Usual Name	Dental Curing Light Device
Regulation Name	Ultraviolet Activator for Polymerization
Regulation Number	21 CFR 872.6070
Product Code	EBZ
Regulatory Class	Class II
Review panel	Dental

IV. DEVICE DESCRIPTION

Cybird is a LED curing light intended for polymerization of light-cured materials by dental professionals. This product is effective on various light-cured materials.
Cybird′s body is made from industrial-grade aluminum which is a durable material intended to ensure heat dissipation. The Cybird features multiple curing modes to ensure functionality.

V. INDICATIONS FOR USE:

The Cybird LED 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 400-480 nm waveband of visible light.

VI. PREDICATE COMPARISON

Descriptive Information	Device: Cybird LED Curing Light Model: Cybird WPT	Device: Cybird LED Curing Light Model: Gold, XD, (K173876)	SE
Intended Use	The Cybird LED 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 400-480 nm waveband of visible light.	The Cybird LED 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 400-480 nm waveband of visible light.	Same
Device Design	**Batteries:** Li-ion with a working voltage of: 3.7V, 2600mAh. Their safety ratings: CE, RoHS, WEEE **Charger**: Inductive Wireless Charger **Power On Button:** Located on the handle of the wand, front and back side	**Batteries:** Li-ion with a working voltage of: 3.7V, 2600mAh. Their safety ratings: CE, RoHS, WEEE **Charger**: 4.2VDC Lithium Ion battery charger **Power On Button:** Located on the handle of the wand, front and back side	**SE1**
Operational modes	High Power Mode: (5, 10, 15, 20 sec) Plasma / Ortho Mode: (3, 6, 9, sec, Ortho mode 55sec) Device indicates illumination time selection	High Power Mode: (5, 10, 15, 20 sec) Plasma / Ortho Mode: (2, 3, 4, sec. Ortho mode 55sec) Device indicates illumination time selection	**SE2**
Light source	LED light, blue and violet Wavelengths 8 light head diameter	LED light, blue and violet Wavelengths 8 light head diameter	Same

Accessories			
Composition of patient contacting Materials	Aluminum, anodized white Barrier Sleeves. Light Shield.	Aluminum, anodized white Barrier Sleeves. Light Shield.	Same
Light Guide	Fiber optic glass Black (11x8, 11x11)	Fiber optic glass Clear (11x8, 11x11)	**SE3**
Light Intensity	Plasma E. Mode / Ortho Mode: 11x8 Black Long(2034mW/Cm2) 11x11 Black Long(1294mW/Cm2) High Power Mode: 11x8 Black Long(1104mW/Cm2) 11x11 Black Long(675mW/Cm2)	Plasma E. Mode / Ortho Mode: 11x8 Clear Shor(2581mW/Cm2) 11x11 Clear Short(1800mW/Cm2) High Power Mode: 11x8 Clear Shor(1521mW/Cm2) 11x11 Clear Short(10430mW/Cm2)W	**SE4**
Peak wavelength	Dual peak: Approximately 405nm, 460nm	Dual peak: Approximately 405nm, 460nm (GOLD), 460nm (XD)	Same
Depth of cure	Plasma mode (3, 6, 9 sec) Spident Escom 100 (K110428): - 11x8 Black: 3.08~4.47 mm - 11x11Black: 2.24 ~ 2.88 mm High Power mode (5,10, 15, 20 sec) Spident Escom 100 (K110428): - 11x8 Black: 3.5~4.99mm - 11x11Black: 3.05~3.95 mm	Plasma mode (2, 3, 4 sec) Spident Escom 100 (K110428): - 11x8 Clear: 3.21~4.12 mm - 11x11Clear: 2.89 ~ 3.45 mm High Power mode (5, 10, 15, 20 sec) Spident Escom 100 (K110428): - 11x8 Clear: 3.78~5.23 mm - 11x11Clear: 3.41~4.45 mm	**SE5**
Parameters of Disinfection	Chemical disinfection with approved cleaning/sanitizing agents: Cavicide products Isopropyl alcohol (75%) Ethyl alcohol based cleaners Lysol disinfectant (alcohol-based only)	Chemical disinfection with approved cleaning/sanitizing agents: Cavicide products Isopropyl alcohol (75%) Ethyl alcohol based cleaners Lysol disinfectant (alcohol-based only)	Same
Usability/Ergonomics	2 buttons – 1 power, 1 mode select	2 buttons – 1 power, 1 mode select	Same
Power source	3.7V Li-ion Battery with inductive wireless charging	3.7V Li-ion Battery	Same

Discussion of the substantial equivalence decision;

Cybird WPT LED Curing Light has identical characteristics and intended uses as the 510(k) cleared light curing units, the Cybird LED curing Light (Model: Gold & XD, K173876), manufactured with identical materials and using the same energy source for the photo-polymerization of dental materials, restorative composite materials and polymerization of bonding and sealing materials.

The intended use of the modified device has not changed.

The differences between the subject and the predicate device are listed below:

SE1	**Device Design**	Wireless Charger: The subject device is equipped with an Inductive Wireless Charger whereas the predicate device has 4.2VDC Lithium Ion battery charger.	The new wireless charger for the subject device delivers the same user convenience of a cordless charger for the predicate device. the spectral irradiance for both devices are identical.
SE2	**Operational modes**	The exposure time in Plasma mode for Cybird WPT has been increased to 3, 6, 9 sec from 2, 3, 4 sec of the predicate device.	A longer light curing time for Plasma mode to achieve equivalent polymerization of RBC of black light guides in comparison with clear light guides,
SE3	**Light Guide**	Fiber optic glass Black	Less light penetration through opaquer shade of a black light guide compared to a clear light guide.
SE4	**Light intensity with Light Guide.**	The irradiance intensity of black light guides for Cybird WPT is about 20~30% lower than the Cybird Gold with clear light guides.	The irradiance intensity of Cybird WPT, the subject device, with a black light guide is about 20~30 % lower than Cybird Gold with a clear light guide.
SE5	**Depth of cure**	Many factors affect the degree of polymerization including the radiant intensity, exposure time and filler type	The depth of cure performances for the subject and predicate device are similar using Spident ESCOM – K110428. Other benefits of lower light intensity with longer exposure time during the resin polymerization are discussed.

The battery charging method is an inductive wireless charger for the subject device and 4.2VDC Lithium Ion battery charger for the predicate device. The exposure time setting for the Plasma mode of the subject device with black guides is also increased to obtain to achieve equivalent polymerization of RBC in comparison with the predicate device with clear light guides.

Cybird WPT is equipped with black light guides, in spite of lower radiant intensity compared to Cybird Gold with a clear light guide, for the following reasons:
The use of black light guides can reduce high intensity light exposure to the eyes of patients and operators through filtering.
Moreover, relatively low radiant intensity over a longer exposure time may improve the uniform distribution and the degree of convergence of dental composites during the resin polymerization process.

These differences do not represent significant issues to clinical evaluation to fulfil the indication for use. In conclusion, the Cybird WPT LED Curing Light is substantially equivalent to the identified predicate device in terms of intended use, materials of construction, performance attributes and technological characteristics.

VII. SUMMARY OF NON-CLINICAL TESTS

Cybird LED Curing Light has been designed and tested according to the FDA guidance for Dental Curing Lights-Premarket Notification. Verification activities included curing hardness, depth of cure per ADA Specification No. 48.

Performance testing
Irradiance intensity test and spectral irradiance output were tested for both devices for comparison. The performance test results demonstrated that the Cybird WPT LED Curing light performed similar or better compared with the predicate device.

In addition, Cybird LED Curing Light complies with voluntary standards for biocompatibility (in vitro cytotoxicity, irritation and sensitization testing), electrical safety and EMC testing. The following data were provided to support the substantial equivalence determination:

Biocompatibility:
Cybird WPT LED Curing Light is manufactured with identical materials as the 510(k) cleared light curing units, the Cybird LED curing Light (Model: Gold & XD, K173876). All materials to be connected to the patient's skin are in conformity with AAMI / ANSI / ISO 10993-5:2009/(R) 2014, Biological Evaluation of Medical Devices-- Part 5: Tests for In Vitro Cytotoxicity (L929 Assay) and AAMI / ANSI / ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

Electrical Safety and EMC essential performance testing was conducted in accordance with
- AAMI ANSI ES 60601-1:2005/(R) 2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
- IEC 60601-1-2 Ed.3: 2007-03 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

Software:
Software verification and validation testing as recommended in IEC62304:2006 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." (May 11, 2005).

VIII. SUMMARY OF CLINICAL TESTS

Clinical testing was not required to demonstrate the substantial equivalence of Cybird WPT LED Curing Light to its predicate device.

IX. CONCLUSIONS

Validation and verification tests have been conducted to FDA guidance document Dental Curing Lights –Premarket Notification [510(k)]. Based on these comparison data, the sponsor believes that Cybird WPT LED Curing Light is substantially equivalent to Cybird Gold / XD LED Curing Light, the predicate device.