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

January 24, 2018

Re: K173876
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: December 27, 2017
Received: January 3, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K173876

Device Name
Cybird LED Curing Light
Model: Cybird GOLD, Cybir XD

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

K173876

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

Date 510k summary prepared: December 29, 2017

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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Official Correspondent	Dave Kim (davekim@mtech-inc.net)
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Telephone/Fax	+713-467-2607 / +713-583-8988

II. DEVICE

Submission Type:	Special 510K
Trade/proprietary Name	Cybird LED Curing Light
Model:	Cybird GOLD / Cybird XD
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

Prescription Use only

III. PREDICATE DEVICE

Primary Manufacturer	DXM Co., Ltd
Trade/proprietary Name	D1 LED Curing Light or SPEC3 or LED 3000
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

Prescription Use only

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Cybird is a LED curing light intended for rapid polymerization of light-cured materials by dental professionals. This product effectively reduces polymerization time on various light-cured materials and provides excellent treatment results every time. Cybird's body is made from industrial-grade aluminum which ensures its durability and excellent heat dissipation. The Cybird features multiple curing modes for maximum functionality.

The Cybird curing light produces visible blue light in the 405 nm (Gold) & 465 nm (Gold / XD) peak waveband of spectrum with a power density of 1,500mW/cm^2 (High Power Mode), 2,500 mW/cm^2 (Ortho Mode, Gold), 2,700mW/cm^2 (Ortho Mode, XD). These power densities are sufficient for the product intended uses.

405 nm (Gold) & 465 nm (Gold / XD) peak waveband of visible light cured (VLC) orthodontic brackets and orthodontic bonding and sealing materials.

Exposure times can be set for 1.5, 2, 2,5, 3 seconds for XD in Ortho Mode; 2, 3, 4 seconds for Gold in Ortho Mode; and 5,10,15, or 20 seconds in High Power Mode.

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 dental curing light**	D1 LED Curing Light or SPEC3 or LED 3000 (K121093)
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 D1 LED Curing Light & accessories is intended to polymerize resinous dental materials, restorative composite materials, orthodontic brackets bonding and sealing materials that are photo-polymerized in the 430-490nm waveband of visible light.
Device Design (operational modes, light source, power source, and accessories)	**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	**Batteries:** Lithium-polymer with a working voltage of: 3.7V, 1200mAh. Their safety ratings: CE, RoHS, WEEE **Charger**: 4.2VDC Lithium Ion battery charger **AC Power Supply**: Input: 100V-240V AC/50/60 Hz Output: +6V DC 2.2A (Bridge power corp – model # JMW118KA0602N01)

		Power On Button: Located on the handle of the wand, back side only
Operational modes	High Power Mode: 1500mW/cm^2 (5, 10, 15, 20 sec) Plasma / Ortho Mode: 2,500 ~2,700mW/cm^2 (2, 3, 4, sec Ortho mode 55sec) Device indicates illumination time selection Device indicates time and time selection	High Power Mode: 1500mW/cm^2 (5,10,20,40 sec) Plasma / Ortho Mode: 3,000mW/cm^2 (1,2,3 sec Ortho mode 55 sec) Device indicates illumination time selection Device indicates time and time selection
Light source	LED light, blue and violet Light guide size (diameter): 8 mm LED Array Manufacturer: ITSWELL Model: IWC-B10C6-VB-JS0303 Rating: Max I_F = 1050mA	LED light, blue and violet Light guide size (diameter): 10mm LED Array Manufacturer: Led Engin Model: LZ4-00B210 Rating Max I_F = 1500mA
Accessories		
Composition of patient contacting Materials	Aluminum, anodized white Barrier Sleeves. Light Shield.	Aluminum, anodized various colors
Light intensity,	Plasma E. Mode / Ortho Mode: 2,500mW/cm2 (2, 3, 4, sec Ortho mode 55sec) High Power Mode: 1,500 mW/cm2 (5, 10, 15, 20 sec)	Plasma / Ortho Mode: 3,000mW/cm^2 (1,2,3 sec) High Power Mode: 1500mW/cm^2 (5,10,20,40 sec)
Peak wavelength	Dual peak: 405nm, 465nm (GOLD) 465nm (XD)	465nm
Depth of cure	Plasma mode (2 sec) - Handae Chemical, Hanfil: 2.270mm - Spident Escom 100 (K110428): 2.100mm - Dentkist Charmfil Plus: 2.380mm - Mediclus Anycom: 2.035mm High Power mode (10 sec) - Handae Chemical, Hanfil: 3.795mm: - Spident Escom 100 (K110428): 3.490mm - Dentkist Charmfil Plus: 3.765mm - Mediclus Anycom: 2.370mm	2.5mm
Parameters of Disinfection	Chemical disinfection with approved cleaning/sanitizing agents: Cavicide products Isopropyl alcohol (75%)	Chemical disinfection with approved cleaning/sanitizing agents: Cavicide products Isopropyl alcohol (75%)

	Ethyl alcohol based cleaners Lysol disinfectant (alcohol-based only)	Ethyl alcohol based cleaners Lysol disinfectant (alcohol-based only)
Usability/Ergonomics	2 buttons – 1 power, 1 mode select	2 buttons – 1 power, 1 mode select

Discussion of the substantial equivalence decision;

The Cybird LED Curing Light has similar characteristics and intended uses as the 510(k) cleared light curing units, the D1 LED Curing Light or SPEC3 or LED 3000 (K121093), 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.
These devices are well established and determined to be safe and effective.
The differences between the subject and the predicate device are the LED light source, light guard diameter, the power mode, and the exposure time.
Luminous/Radiant Flux for Cybird LED Curing Light is lower compared to the predicate device. However, light is distributed evenly on the exposure surface whereas the predicate device's light intensity is higher on the center of the surface.
These differences thus raise no new questions of safety and effectiveness and do not represent significant issues to clinical evaluation to fulfil the indication for use. In conclusion, the Cybird LED Curing Light is substantially equivalent to the identified predicate device in regard to intended use, materials of construction, performance attributes and technological characteristics.

Furthermore, the intended use of the modified device has not changed as a result of the modifications.

VII. SUMMARY OF NON-CLINICAL TESTS

The 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, maximum light intensity measurements at 2 mm for all power modes, and spectral irradiation plots of all power modes.
The 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:
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. The difference of material used between subject and predicate device does not affect safety and effectiveness.

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 the Cybird LED Curing Light to its predicate device.

IX. CONCLUSIONS

Based on the information above, the sponsor believes that Cybird LED Curing Light is substantially equivalent to the predicate device. The differences between the Cybird LED Curing Light and its predicate do not raise different questions of safety and effectiveness.