K12 1093

dxm

Section 3: 510(k) Summary

NOV 2 7 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

1. **Submitter's Identification:**

DXM Co., Ltd.
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Baeksuk1-Dong, Ilsandong-Gu,
Goyang-City
Republic of Korea 410-722
Telephone – 82 31 909-8275
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Contact – Sun Hwa Song, Chief Officer

Date Summary Prepared: April 9, 2012

2. **Name of Device:**

Trade/Proprietary Name:

D1 LED Curing Light
SPEC 3
Dentronix LED 3000

Classification Name:

Activator, Ultraviolet, for Polymerization

Class in which Device has been placed:

The Dental devices panel has classified this device as Class II, 21 CFR Part 872.6070, Product Code EBZ.

3. **Predicate Device Information:**

The D1 LED Curing Light is substantially equivalent to:

- Cybird LED curing light (K042703)
- Coltolux LED (K040551)
- Valo Cordless (K110582)

4. Device Description:

D1 by DXM Co., Ltd. is classified as an Ultraviolet Activator for polymerization (21 CFR 872.6070) because it is a device intended for the photo-polymerization light cured dental materials. The D1-Cordless is a universal photo-polymerization light curing source working in cordless conditions and producing visible blue light in the 430 to 490nm waveband of spectrum with a power density of 3,000mW/cm^2 (11-8mm light-guide). These power densities are sufficient for the product intended uses, namely, Photo-polymerization in the 430-490 nm waveband of visible light cured (VLC) dental materials, restorative composite materials, and orthodontic brackets and orthodontic bonding and sealing materials.
D1 has two operating modes: Plasma Emulation/ Ortho mode: 3000 mW/cm^2 and High Power mode: 1500 mW/cm^2.
Exposure timing intervals for Plasma Emulation mode is 1, 2, 3 seconds, Ortho: approximately 3 seconds on, 1 second off for 16 cycles and High Power mode: 5, 10, 20, 40 seconds.

The D1 Curing light is cordless and is powered by a rechargeable Lithium-Ion battery which is charged by a Battery Charger Stand supplied with a certified AC/DC Adapter.

5. Indication for Use:

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.

6. Substantial Equivalence:

The DXM D1 LED curing light has similar characteristics and intended use as previously cleared device, K042703 Cybird LED curing light, Coltolux LED (K040551) and Valo Cordless (K110582) 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.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing that was conducted in accordance with IEC 60601-1: 1988 +A1 1991,+A2 1995; ANSI/AAMI/IEC 60601-1-2: 2007; supports testing information demonstrating safety and effectiveness of the D1-Cordless LED Curing Light in the intended environment of use. Biocompatibility testing conducted based on ISO 10993-5 and ISO 10993-10.
Non-clinical Bench Test performed as following:

- Verification Spectral Irradiance output
- Verification/ Validation of Irradiance Intensity
- Depth of Cure
- Verification of case Temperature Rise

None of the testing demonstrated any design characteristics that violated the requirements of the standards or resulted in any safety hazards.

7. Discussion of Clinical Tests Performed:

No clinical testing was conducted.

8. Conclusions:

The D1-Cordless LED Curing Light is substantially similar to the predicate in intended use, operation, safety and function, and is safe and effective for its' intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DXM Company, Limited
C/O Mr. Jigar Shah
MDI Consultants, Incorporated
55 Northern Boulevard
Great Neck, New York

NOV 2 7 2012

Re: K121093
Trade/Device Name: D1 LED Curing Light or SPEC 3 or LED 3000
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: October 25, 2012
Received: October 26, 2012

Dear Mr. Shah:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Digitally signed by Kwame O. Ulmer
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kwame O. Ulmer, 0.9.2342.19200300.100.1.1=1300183618
Date: 2012.11.26 14:56:21 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

dxm

Section 2: Indications for Use

510(k) Number (if known): K121093

Device Name: D1 LED Curing Light or SPEC 3 or LED 3000

Indications For Use:

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.

Susan Runner DDS, MA 2012.11.27 13:38:28 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number:

Prescription Use X (Per 21 CFR 801 Subpart D) OR Over-The Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)