DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DENTALL Co., Ltd
c/o DongHa Lee
KMC, Inc.
Room no., 904, 27, Digital-ro 27ga-gil, Guro-gu
Seoul 08375
KOREA

August 8, 2017

Re: K170529
Trade/Device Name: Delight, Delight Ortho, B&Lite S
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet activator for polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: June 23, 2017
Received: July 5, 2017

Dear DongHa Lee:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Mary S. Runner -S

Michael Ryan
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170529

Device Name
Delight, Delight ortho, B&Lite S

Indications for Use *(Describe)*
For light curing polymerization of dental composites, luting materials, cements and other light cured materials

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 (K170529)

Date: August 9, 2017

1. Applicant / Submitter

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Establishment registration number: 3009307635

2. Submission Contact Person

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3. Device Information

- Trade Name: Delight, Delight ortho, B&Lite S
- Common Name: Dental curing light
- Device Classification: Class II
- Classification Name: Ultraviolet activator for polymerization
- Product Code: EBZ
- Classification regulation: 21CFR 872.6070

4. Predicate Device

- Hi-Light, Hi-Light plus (K140432) by DENTALL Co., Ltd.

5. Device Description

Delight, Delight ortho and B&Lite S are light-emitting diode (LED) type dental curing light that is

used for polymerization of light cure resin based composites. They can be used on several different dental materials that are curable by light. The devices use LED that produce a narrow spectrum of blue light in the 430~490nm range, which is useful energy range for activating the CPQ molecule, most commonly used to initiate the photo polymerization of dental monomers. The devices are designed by considering lightweight and portability. They operate on a rechargeable battery, making it easier to carry and use.
The device is not provided sterile and is not intended to be sterilized when used. To prevent cross contamination, users must cover the device with FDA cleared barrier sheath (K132953/ TIDIShield™ Curing Light Sheath). It should be changed between each patient.

6. Indication for use

For light curing polymerization of dental composites, luting materials, cements and other light cured materials.

7. Substantial Equivalence

Delight, Delight ortho and B&Lite S are substantially equivalent to the predicate devices, Hi-Light, Hi-Light plus (K140432) by DENTALL 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**	
Device Name	Delight	Delight ortho	B&Lite S	Hi-Light	Hi-Light plus
Manufacturer	DENTALL Co., Ltd.			DENTALL Co., Ltd.	
510(k) number	-			K140432	
Product Code	EBZ			EBZ	
Regulatory Class	2			2	
Indications for use	For light curing polymerization of dental composites, luting materials, cements and other light cured materials.			For light curing polymerization of dental composites, luting materials, cements and other light cured materials.	
Device Design - Operation Mode (Standard / Normal Power Mode)	1) Optical output: 1,200 mW/cm²(±10%) 2) Available time setting: 5, 10, 15, 20 seconds	1) Optical output: 1,200 mW/cm²(±10%) 2) Available time setting: 5, 10, 15, 20 seconds	1) Optical output: 800 mW/cm²(±10%) 2) Available time setting: 5, 10, 15, 20 seconds	1) Optical output: 700 mW/cm²(±10%) 2) Available time setting: 10, 15, 20, 30 seconds	1) Optical output: 1,000 mW/cm²(±10%) 2) Available time setting: 5, 10, 15, 20 seconds
Device Design - Operation Mode (High / Fast Power	1) Optical output: 1,800 mW/cm²(±10%) 2) Available time	1) Optical output: 2,700 mW/cm²(±10%) 2) Available time	1) Optical output: 1,200 mW/cm²(±10%) 2) Available time	1) Optical output: 1,400 mW/cm²(±10%) 2) Available time	1) Optical output: 1,600 mW/cm²(±10%) 2) Available time

Mode)	setting: 3, 6, 9, 12 seconds	setting: 2, 3, 5, 10 seconds	setting: 3, 6, 9, 12 seconds	setting: 5, 10, 15, 20 seconds	setting: 3, 5, 10, 15 seconds
Device Design - Operation Mode (Soft Start Mode)	1) Optical output: After gradually increasing from 0 to 1,800 mW/cm²(±10%) and be maintained until finish time 2) Available time setting: 5, 10, 15 seconds	-	1) Optical output: After gradually increasing from 0 to 1,200 mW/cm²(±10%) and be maintained until finish time 2) Available time setting: 5, 10, 15 seconds	1) Optical output: After gradually increasing from 0 to 2,000 W/cm²(±10%) and be maintained until finish time 2) Available time setting: 10, 15, 20 seconds	1) Optical output: After gradually increasing from 0 to 1,600 mW/cm²(±10%) and be maintained until finish time 2) Available time setting: 5, 10, 15 seconds
Device Design - Operation Mode (Pulse / Sequential Power Mode)	1) Optical output: Repeat 0 and 1,800 mW/cm²(±10%) continuously 2) Available time setting: 10, 15, 20 seconds	1) Optical output: 2,700 mW/cm²(±10%). Repeat it 8 times at intervals of 2 second. 2) Available time setting: 2, 3, 4, 5 seconds	-	1) Optical output: Repeat 0 and 2,000 mW/cm²(±10%) continuously 2) Available time setting: 10, 15, 20 seconds	1) Optical output: 2,700 mW/cm²(±10%). Repeat it 8 times at intervals of 2 second. 2) Available time setting: 1, 2, 3, 4 seconds
Device Design - Operation Mode (General Orthodontic / Turbo Mode)	-	-	1) Optical output: 1,800 mW/cm²(±10%) 2) Available time setting: 2, 4, 6 seconds	1) Optical output: 2,000 mW/cm²(±10%) 2) Available time setting: 3, 5, 10, 15 seconds	-
Device Design - Operation Mode (Fast Orthodontic / Extra Mode)	-	-	1) Optical output: 2,700 mW/cm²(±10%) 2) Available time setting: 1, 2, 3 seconds	-	1) Optical output: 3,000 mW/cm²(±10%) 2) Available time setting: 1, 2, 3, 4 seconds
Device Design - Light source	10W LED			10W LED	
Device Design - Power source of handpiece	Rechargeable Li-ion battery (3.7Vdc. 2200mAh)			Rechargeable Li-ion battery (3.7Vdc)	
Device Design - Power source of battery charger	AC/DC Adapter (Input: 100-240Vac, 50/60 Hz, 400 mA Output: 5.0Vdc, 1.6A)			AC/DC Adapter (Input: 100-240Vac, 50/60 Hz, 400 mA Output: 5.0Vdc)	

Device Design - Accessories	Handpiece , Battery charger, Battery pack, Anti- glare shield, Light guide, AC/DC adapter			Handpiece , Battery charger, Battery pack, Anti- glare shield, Light guide, AC/DC adapter	
Chemical composition of patient contacting portions of the device	Disposable sheath (FDA cleared barrier sheath, K132953/ TIDIShieldTM Curing Light Sheath)			Disposable sheath (FDA cleared barrier sheath)	
Technical Specifications - Light intensity	Max. 1,800mW/cm² (±10%)	Max. 2,700mW/cm² (±10%)	Max. 2,700mW/cm² (±10%)	Max. 2,000mW/cm² (±10%)	Max. 3,000mW/cm² (±10%)
Technical Specifications - Wavelength range	430 ~ 490nm			430 ~ 490nm	
Technical Specifications - Peak wavelength-	460nm			460nm	
Compliance to FDA-Recognized Standards	IEC 60601-1:2005 + A1:2012 IEC 60601-1-2:2007 ADA/ANSI Specification No.48, ANSI/ADA Standard No. 48-2			IEC 60601-1:2005 IEC 60601-1-2:2007 ADA/ANSI Specification No.48, ANSI/ADA Standard No 48-2	

7.1 The same between the subject device and the predicate devices.

1) Product Code and Regulatory Classification
: The proposed classification of the subject devices is 2 according to the product code, EBZ. It is the same as the predicate devices (K140432).

2) Indications for Use
: The proposed indications for use of the subject devices is for light curing polymerization of dental composites, luting materials, cements and other light cured materials. It is the same as the predicate devices (K140432).

3) Principle of Operation
: The subject devices are light-emitting diode (LED) type cordless dental curing light that produce a narrow spectrum of blue light in the 430~490nm range, which is useful energy range for activating the CPQ molecule, most commonly used to initiate the photo polymerization of dental monomers. It is the same as the predicate devices (K140432).

4) Light Source

: The subject device uses 10W LED that produce a narrow spectrum of blue light in the 430~490nm wave range and 460nm peak wavelength. It is the same as the predicate devices (K140432).

5) Power Source
: The subject device is handpiece type using an internal rechargeable lithium ion battery (3.7Vdc. 2200mAh) and a battery charger (AC/DC Adapter, Input: 100-240Vac, 50/60 Hz, 400 mA Output: 5.0Vdc, 1.6A) is provided by manufacturer. It is the same as the predicate devices (K140432).

6) Chemical composition of patient contacting portions of the device
: The subject device uses a disposable sheath (FDA cleared barrier sheath, K132953/ TIDIShield™ Curing Light Sheath). It is the same as the predicate devices (K140432).

7.2 Differences between Subject Devices and Predicates Devices

1) Operation Modes and Light Intensity
: 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 difference do not raise any problems in the safety and performance.

2) Depth of cure
: The subject devices specify several depth of cure corresponding to the operation mode. The depth of cure was evaluated according to 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 difference do not raise any problems in the safety and performance.

8. Electrical Safety and Electromagnetic compatibility

The Electrical Safety and Electromagnetic compatibility tests were performed in accordance with the following standards.

- IEC 60601-1:2005+A1:2012 and US Deviation (AAMI/ANSI ES 60601-1: 2005+A1: 2012), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

The test results conformed to the standards.

9. Performance Testing – Nonclinical Testing

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

- Irradiation (Optical Power Testing)
- Spectral irradiance plot (Wavelength Spectrum Testing)
- 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: 2004, Reaffirmed 2015, Visible Light Curing Units
- American National Standard/American Dental Association (ANSI/ADA) Specification No. 48-2: 2010, Reaffirmed 2015, LED Curing Lights
- 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

In comparing between the subject devices and the predicate devices, there are the same product code, regulatory classification, indications for use, principle of operation, light source, power source, and chemical composition of patient contacting portions. Safety and performance testing supports substantial equivalence of the subject device to the predicate devices.