DENTALL Co., Ltd

c/o DongHa Lee

KMC, Inc.

Room no., 904, 27, Digital-ro 27ga-gil, Guro-gu

Seoul 08375

KOREA

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

August 8, 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

<table>
<thead>
<tr>
<th>Version</th>
<th>Document Author</th>
<th>Document Approver</th>
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<td>1.00</td>
<td>Name, Title, Office</td>
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Complete Change Control Table (all versions) retained in SWIFT Docs.
Indications for Use

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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   Tel: +82-32-327-6026    Fax: +82-32-327-6027
   Establishment registration number: 3009307635

2. Submission Contact Person
   DongHa Lee (Consultant / KMC, Inc.)
   Address: Room no. 904, 27, Digital-ro 27ga-gil, Guro-gu, Seoul, 08375, Korea
   Tel: +82-70-8965-5554    Fax: +82-2-2672-0579
   Email: dhlee@kmcerti.com

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.

<table>
<thead>
<tr>
<th>Descriptive Information</th>
<th>Subject Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name</td>
<td>Delight</td>
<td>Delight ortho</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>DENTALL Co., Ltd.</td>
<td></td>
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<tr>
<td>510(k) number</td>
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<tr>
<td>Product Code</td>
<td>EBZ</td>
<td>EBZ</td>
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<tr>
<td>Regulatory Class</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Indications for use</td>
<td>For light curing polymerization of dental composites, luting materials, cements and other light cured materials.</td>
<td>For light curing polymerization of dental composites, luting materials, cements and other light cured materials.</td>
</tr>
<tr>
<td>Device Design - Operation Mode (Standard / Normal Power Mode)</td>
<td>1) Optical output: 1,200 mW/cm² (±10%) 2) Available time setting: 5, 10, 15, 20 seconds</td>
<td>1) Optical output: 1,200 mW/cm² (±10%) 2) Available time setting: 5, 10, 15, 20 seconds</td>
</tr>
<tr>
<td>Device Design - Operation Mode (High / Fast Power Mode)</td>
<td>1) Optical output: 1,800 mW/cm² (±10%) 2) Available time</td>
<td>1) Optical output: 2,700 mW/cm² (±10%) 2) Available time</td>
</tr>
<tr>
<td>Mode)</td>
<td>setting: 3, 6, 9, 12 seconds</td>
<td>setting: 2, 3, 5, 10 seconds</td>
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</tr>
<tr>
<td>Device Design - Operation Mode (Soft Start Mode)</td>
<td>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</td>
<td>-</td>
</tr>
<tr>
<td>Device Design - Operation Mode (Pulse/Sequential Power Mode)</td>
<td>1) Optical output: Repeat 0 and 1,800 mW/cm² (±10%) continuously 2) Available time setting: 10, 15, 20 seconds</td>
<td>1) Optical output: Repeat 2,700 mW/cm² (±10%). Repeat it 8 times at intervals of 2 second. 2) Available time setting: 2, 3, 4, 5 seconds</td>
</tr>
<tr>
<td>Device Design - Operation Mode (General Orthodontic / Turbo Mode)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Device Design - Operation Mode (Fast Orthodontic / Extra Mode)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Device Design - Light source</td>
<td>10W LED</td>
<td>10W LED</td>
</tr>
<tr>
<td>Device Design - Power source of handpiece</td>
<td>Rechargeable Li-ion battery (3.7Vdc. 2200mAh)</td>
<td>Rechargeable Li-ion battery (3.7Vdc)</td>
</tr>
<tr>
<td>Device Design - Power source of battery charger</td>
<td>AC/DC Adapter (Input: 100-240Vac, 50/60 Hz, 400 mA  Output: 5.0Vdc, 1.6A)</td>
<td>AC/DC Adapter (Input: 100-240Vac, 50/60 Hz, 400 mA  Output: 5.0Vdc)</td>
</tr>
</tbody>
</table>
## 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/ TIDIShield™ Curing Light Sheath)

Disposable sheath
(FDA cleared barrier sheath)

## Technical Specifications - Light intensity

<table>
<thead>
<tr>
<th></th>
<th>Max. 1,800mW/cm² (±10%)</th>
<th>Max. 2,700mW/cm² (±10%)</th>
<th>Max. 2,700mW/cm² (±10%)</th>
<th>Max. 2,000mW/cm² (±10%)</th>
<th>Max. 3,000mW/cm² (±10%)</th>
</tr>
</thead>
</table>

## Technical Specifications - Wavelength range

430 ~ 490nm

430 ~ 490nm

## Technical Specifications - Peak wavelength

460nm

460nm

## Compliance to FDA-Recognized Standards

- 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

### 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.


The test results conformed to the standards.

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.

- 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.