DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 3, 2015

Dentall Corporation
c/o Ms. Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave. Suite 110
Fullerton, California 92831

Re: K140432
Trade/Device Name: Hi-light, Hi-light Plus
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: July 3, 2015
Received: July 6, 2015

Dear Ms. Chung:

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" (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.

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 yours,

for Erin I. Keith, M.S.
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140432

Device Name
Hi-Light, Hi-Light plus

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

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

Date: 08/03/2015

1. Applicant / Submitter

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2. Submission Contact Person

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3. Device

- Trade Name: Hi-Light, Hi-Light plus
- 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

- Primary Predicate Device: Bluephase 16i (K051782) by IVOCLAR VIVADENT, Inc.
- Reference Predicate Device: VALO Cordless (K110582) by Ultradent Products, Inc.

5. Description

Hi-Light and Hi-Light plus 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 420~490nm 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.

6. Indication for use:

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

7. Basis for Substantial Equivalence

Hi-Light and Hi-Light plus are substantially equivalent to the Bluephase 16i (K051782) by IVOCLAR VIVADENT, INC and VALO Cordless (K110582) by Ultradent Products, Inc. in terms of intended use, technology and principle of operation. The difference is in different modes but the light intensity (mW/cm²) of the predicate devices encompass the range of the subject device; therefore we determine that this difference in modes do not raise issues of substantial equivalence.

	Subject Device		**Primary Predicate Device**	**Reference Predicate Device**
Device Name	Hi-Light	Hi-Light plus	Bluephase 16i	VALO Cordless
Manufacturer	DENTALL Corporation	DENTALL Corporation	IVOCLAR VIVADENT, INC	Ultradent Products, Inc.
510(k) number	-	-	K051782	K110582
Product Code	EBZ	EBZ	EBZ	EBZ
Regulatory Class	II	II	II	II
Intended 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.	For light curing polymerization of dental composites, luting materials, cements and other light cured materials.	Source of illumination for curing photo-activated dental restorative materials and adhesives.
Device Design (operational mode 1)	Normal Mode 1) Optical output: 700 mW/cm² (±10%) 2) Available time setting: 10, 15, 20, 30 seconds	Normal Mode 1) Optical output: 1,000 mW/cm² (±10%) 2) Available time setting: 5, 10, 15, 20 seconds	Low Power mode 1) Optical output: 650 mW/cm² (±10%) 2) Available time setting: 10, 20, 30 seconds	Standard Power Mode 1000mW/ cm²
Device Design (operational mode 2)	High Mode 1) Optical output: 1,400 mW/cm² (±10%) 2) Available time setting: 5, 10, 15, 20 seconds	High Mode 1) Optical output: 1,600 mW/cm² (±10%) 2) Available time setting: 3, 5, 10, 15 seconds	High Power mode 1) Optical output: 1,600 mW/cm² (±10%) 2) Available time setting: 5, 10 seconds	High Power Mode 1400mW/cm²
Device Design (operational mode 3)	Turbo Mode 1) Optical output: 2,000 mW/cm² (±10%) 2) Available time setting: 3, 5, 10, 15 seconds	Extra Mode 1) Optical output: 3,000 mW/cm² (±10%) 2) Available time setting: 1, 2, 3, 4 seconds	-	Xtra Power Mode 3200mW/cm²
Device Design (operational mode	Soft Start Mode 1) Optical output: After	Soft Start Mode 1) Optical output: After	Soft Start Mode 1) Optical output: After	-

4)	gradually increasing from 0 to 2,000 W/cm² (±10%) and be maintained until finish time 2) Available time setting: 10, 15, 20 seconds	gradually increasing from 0 to 1,600 mW/cm² (±10%) and be maintained until finish time 2) Available time setting: 5, 10, 15 seconds	gradually increasing from 0 to 650 mW/cm² (±10%) and jump to 1,600 W/cm². It is maintained until finish time 2) Available time setting: 10, 15 seconds	
Device Design (operational mode 5)	Pulse Mode 1) Optical output: Repeat 0 and 2,000 mW/cm² (±10%) continuously 2) Available time setting: 10, 15, 20 seconds	Sequential power Mode 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 (light source)	10W LED	10W LED	10W LED	LED
Device Design (power source of handpiece)	Rechargeable Li-ion battery (3.7Vdc)	Rechargeable Li-ion battery (3.7Vdc)	Rechargeable Li-ion battery (7.2Vdc) Power pack (12Vdc)	Rechargeable Li-ion battery (3.2Vdc)
Device Design (power source of Battery charger)	AC/DC Adapter (Input: 100-240Vac, 50/60 Hz, 400 mA Output: 5.0Vdc)	AC/DC Adapter (Input: 100-240Vac, 50/60 Hz, 400 mA Output: 5.0Vdc)	AC/DC Adapter (Input: 100-240 Vac, 50-60 Hz, 350 mA Output 12Vdc)	AC/DC Adapter (Input: 100-240 Vac, 50-60 Hz, 500 mA Output 12Vdc)
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	Handpiece , Battery charger, Battery pack, Anti- glare shield, Light guide, AC/DC adapter	Handpiece , Battery charger, Battery pack, Light guide, AC/DC adapter
Chemical composition of patient contacting portions of the device	FDA cleared barrier sleeve	FDA cleared barrier sleeve	Glass	FDA cleared barrier sleeve
Technical Specifications (light intensity)	Max 2,000 mW/cm² (±10%)	Max 3,000 mW/cm² (±10%)	Max. 1,600 mW/cm² (± 100 mW/cm²)	Max. 3,200 mW/cm² (± 20%)
Technical Specifications (wavelength range)	430 ~ 490nm	430 ~ 490nm	430 ~ 490nm	395 ~ 480nm
Technical Specifications (peakwave length)	460nm	460nm	460nm	Unknown
Technical Specifications (depth of cure)	Normal Mode: 5.5mm High Mode: 5.7mm Turbo Mode: 4.5mm Soft Start Mode: 6.3mm Pulse Mode: 4.9mm	Normal Mode: 4.6mm High Mode: 4.4mm Extra Mode: 5.0mm Soft Start Mode: 4.5mm Sequential power Mode: 4.4mm	-	-
Compliance to FDA-Recognized Standards	IEC 60601-1: 2005 IEC 60601-1-2: 2007 ADA/ANSI Specification No.48 Visible Light	IEC 60601-1: 2005 IEC 60601-1-2: 2007 ADA/ANSI Specification No.48 Visible Light	IEC 60601-1: 2005 IEC 60601-1-2: 2007 ADA/ANSI Specification No.48 Visible Light	IEC 60601-1: 2005 IEC 60601-1-2: 2007 ADA/ANSI Specification No.48 Visible Light

	Curing Units, ANSI/ADA Standard No 48-2 LED Curing Lights	Curing Units, ANSI/ADA Standard No 48-2 LED Curing Lights	Curing Units, ANSI/ADA Standard No 48-2 LED Curing Lights	Curing Units, ANSI/ADA Standard No 48-2 LED Curing Lights

8. Non-Clinical Testing

The non-clinical tests were performed on the subject device in accordance with the following standards and the test results met the pre-set criteria.

- American National Standard/American Dental Association (ANSI/ADA) Specification No. 48: 2004
- American National Standard/American Dental Association (ANSI/ADA) Specification No. 48-2: 2010
- IEC 60601-1: 2005, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2: 2007, Medical Electrical Equipment - Part 1-2 : General Requirements for Safety – Collateral Standard : Electromagnetic compatibility-requirements
- ISO 10993-5:2009/(R) 2014, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity (Biocompatibility)
- ISO 10993-10 Third Edition 2010-08-01, biological evaluation of medical devices - part 10: tests for irritation and skin sensitization (Biocompatibility)

9. Conclusion

The subject devices and the predicate devices have the same intended use and have the same technological characteristics. Overall, the Hi-Light and Hi-Light plus have the following similarities to the predicate devices:

* have the same intended use,
* use the same operating principle,
* incorporate the same basic design,
* have similar performance specifications.

Based on the similarities, we conclude that the Hi-Light and Hi-Light plus are substantially equivalent to the predicate devices.