

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

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 <u>Federal Register</u>.

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

<u>http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</u> 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,

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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

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

DENTALL Corporation 301-905 Techno-park, 365 Samjeong-dong, Ojeong-gu, Kyunggi, Republic of Korea 421-741 Tel : +82-32-327-6026 Fax : +82-32-327-6027

2. Submission Contact Person

Priscilla Juhee Chung LK Consulting Group USA, Inc. 2651 E Chapman Ave Ste 110, Fullerton, CA 92831 Phone: 714.202.5789 Fax: 714-409-3357 Email: juhee.c@lkconsultinggroup.com

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	П	П	П	П
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/cm ² (±10%) 2) Available time setting: 10, 15, 20, 30 seconds	Normal Mode 1) Optical output: 1,000 mW/cm ² (±10%) 2) Available time setting: 5, 10, 15, 20 seconds	Low Power mode 1) Optical output: 650 mW/cm ² (±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/cm ² (±10%) 2) Available time setting: 5, 10, 15, 20 seconds	High Mode 1) Optical output: 1,600 mW/cm ² (±10%) 2) Available time setting: 3, 5, 10, 15 seconds	High Power mode 1) Optical output: 1,600 mW/cm ² (±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/cm ² (±10%) 2) Available time setting: 3, 5, 10, 15 seconds	Extra Mode 1) Optical output: 3,000 mW/cm ² (±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	-

510(k) Submission.

510(k) Summary , $2\,/\,4\,\,page$

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Device Design (power source of Battery charger)(Input: 100-240Vac, 50/60 Hz, 400 mA Output: 5.0Vdc)(Input: 100-240 Vac, 50/60 Hz, 50/60 Hz, 60 Hz, 350 mA Output 12Vdc)(Input: 100-240 Vac, 50- 60 Hz, 350 mA Output 12Vdc)(Input: 120-240 Vac, 50- 60 Hz, 350 mA Battery charger, Battery charger, Battery charger, Battery charger, Battery pack, Ac/DC adapterHandpiece - Battery charger, Battery charger, Battery pack, Ac/DC adapterHandpiece - Battery charger, Battery charger, Battery charger, Battery charger, Battery charger, Battery charg		AC/DC Adomton	AC/DC Adomton	• · · · · · · · · · · · · · · · · · · ·	
(power source of Battery charger)50/60 Hz, 400 mA100-240 Vac, 30- 60 Hz, 300- 60 Hz, 300- Mutual 12 Vdc)(Input 12 Vdc) 60 Hz, 300- 60 Hz, 300- Mutual 12 Vdc)Device Design (accessories)Handpiece , Battery pack, Anti-glare shield, Light guide, AC/DC adapterHandpiece , Battery pack, Anti-glare shield, Light guide, AC/DC adapterHandpiece , Battery pack, AC/DC adapterChemical specifications (light intensity)FDA cleared barrier (±10%)FDA cleared barrier (±10%)Handpiece , Handpiece , Max 3,000 mW/cm2 (±10%)Max 1,600 mW/cm2 (±100 mW/cm2 (±20%)Max 3,200	Dovice Design		1		
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510(k) Submission.

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