April 29, 2019

Ultradent Products, Inc.
Karen Kakunes
Regulatory Affairs Manager
505 West Ultradent Drive (10200 South)
South Jordan, Utah 84095

Re: K190627
Trade/Device Name: VALO Grand Corded
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: March 8, 2019
Received: March 12, 2019

Dear Karen Kakunes:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190627

Device Name
VALO Grand Corded

Indications for Use *(Describe)*
The source of illumination for curing photo-activated dental restorative materials and adhesives.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K190627

Special 510(k) Summary for VALO® Grand Corded

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92 for VALO® Grand Corded.

I. Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095
FDA Establishment Registration #: 1718912

Contact Person: Ms. Karen Kakunes
Title: Regulatory Affairs Manager
Telephone: 801-553-4366
FAX: 801-553-4609

Date Summary Prepared: 22 April 2019

II. Name of the Device

Trade Name: VALO® Grand Corded
Common Name: Dental Curing Light
Device Classification: Class II
Classification Product Code: EBZ
Classification Name: Ultraviolet Activator for Polymerization
Regulation No. 21 CFR 872.6070

III. Device Description:

VALO® Grand Corded is a mains-powered, visible light activator for polymerization of dental resins of all photo-initiated dental materials. The VALO® Grand Corded version functions the same as the predicate, VALO® (K083647), as a professional hand-held, LED-based, visible light curing device. The modified device, VALO® Grand Corded, is manufactured from the same materials (anodized aluminum, rubber buttons, LED light source, printed circuit board, silicone adhesive, plastic), is used for the same indications, and has the same intended use as the predicate device. Both devices have three power output modes ranging from 800 – 2300 mW/cm2. Both the new device and predicate cure dental composite materials in the 395 – 480 nm range using an LED light source. Differences from the predicate include an increased light head diameter to provide a larger curing area over a tooth, an additional LED activation ('power') button, and the middle power mode setting has been increased to make it more central between the Standard and Xtra Power modes. Additionally, VALO Grand Corded will include one pair of Blue Light Blocking Glasses, which will replace the Light Shield.

IV. Indications for Use:

The source of illumination for curing photo-activated dental restorative materials and adhesives.

V. Predicate Device:

The primary predicate device, VALO®, K083647, 23 Jan 2009 and reference device VALO Grand, K160551, 13 Jul 2016.

VI. Identification of Risk Analysis Method:

Risk Analysis was performed on VALO® Grand Corded utilizing processes based on ISO 14971. Risks associated to patient safety and product efficacy for VALO® Grand Corded have been identified, assessed, and mitigated to a substantially equivalent level.

VII. Comparison of Technological Characteristics

VALO® Grand Corded and VALO® have similar technological characteristics as described in Table 5.1.

Table 5.1: Substantial equivalence comparison

Descriptive Information	**Device: VALO® Grand Corded dental curing light**	**Predicate: VALO® dental curing light (K083647)**
Indications for Use	The source of illumination for curing photo-activated dental restorative materials and adhesives.	The source of illumination for curing photo-activated dental restorative materials and adhesives.
Principle of Operation	Hand-held professional dental curing light which emanates light energy with peak wavelengths between 395 - 480 nm range from an LED light source which cures photocurable, polymer resin-based dental restorative materials	Hand-held professional dental curing light which emanates light energy with peak wavelengths between 395 - 480 nm range from an LED light source which cures photocurable, polymer resin-based dental restorative materials
Intended User	Dentist or dental professional	Dentist or dental professional
Power source	Wall powered, 9VDC, medical grade with adapters for international capability UL Approved	Wall powered, 9VDC, medical grade with adapters for international capability UL Approved
Operational modes	*Standard Power Mode: 1000 mW/cm^2	*Standard Power Mode: 1000 mW/cm^2

Descriptive Information	Device: VALO® Grand Corded dental curing light	Predicate: VALO® dental curing light (K083647)
	*High Power Plus Mode: 1600mW/cm^2 Xtra Power Mode: 3200mW/cm^2 Device indicates illumination time selection Device indicates time and time selection *as measured by Demetron	*High Power Mode: 1400mW/cm^2 Xtra Power Mode: 3200mW/cm^2 Device indicates illumination time selection Device indicates time and time selection *as measured by Demetron
Light source	LED light, blue and violet wavelengths 12mm head size	LED light, blue and violet wavelengths 10 mm head size
Accessories	Barrier Sleeve VALO®, Blue-Light Blocking Glasses	Barrier Sleeve VALO®, VALO® Light Shield
Composition of Materials	Aluminum, anodized black	Aluminum, anodized black
Acceptable Cleaners	Acceptable Cleaners: Lysol Brand III Disinfectant Spray (Recommended) Cavicide products (non-bleach) Isopropyl alcohol Ethyl alcohol-based cleaners Lysol Concentrate (alcohol-based only)	Anti-microbial surface disinfectant DO NOT autoclave. DO NOT immerse in any kind of ultrasonic batch or any liquids.
Usability/Ergonomics	3 buttons – 2 power, 1 mode select	2 buttons – 1 power, 1 mode select

As outlined in the comparison tables above, VALO® Grand Corded is similar to the primary predicate, VALO® (K083647), in technology and identical in indications for use, power source, depth of cure, peak wavelength, and similar light source (LED). VALO® Grand Corded is used and cleaned in the same way by the same type of users. VALO Grand (K160551) is included as a reference device for the difference in head size between the subject device and the primary predicate.

The major functional changes between the submitted device, VALO® Grand Corded and the predicate device VALO® is in the light head diameter (12 mm vs 10 mm), an additional LED activation button, and the change in intensity of the High Power Plus (middle) mode setting (1600 mW/cm^2 vs. 1400 mW/cm^2). The VALO® Blue-Light Blocking Glasses were not included as part of the original VALO® submission. However, the original submission included a recommended light shield attachment as an accessory during use. VALO® Grand Corded is replacing the light shield supplied with the device to instead include Blue-Light Blocking Glasses. These differences do not impact safety and effectiveness based on validation and verification activities described below.

Device design validation and verification activities have been performed to FDA Guidance Document Dental Curing Lights – Premarket Notification [510(k)] and recognized standards, including ADA , where available, and via internal testing protocols. Results confirm that VALO® Grand Corded performs equivalently to the predicate VALO® with the modifications that have been made.

Based on these comparisons to already-cleared predicate device, we believe that VALO® Grand Corded is substantially equivalent to VALO®.