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

July 13, 2016

Ultradent Products, Inc.
Mr. Corey Jaseph
Regulatory Affairs Manager
505 West 10200 South
South Jordan, Utah 84095

Re: K160551
Trade/Device Name: Valo® Grand
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: May 25, 2016
Received: June 14, 2016

Dear Ms. Jaseph:

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

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095
Est. Reg. No. 1718912

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)*

K160551

Device Name
VALO Grand

Indications for Use *(Describe)*

The VALO Grand is a 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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Special 510(k) Summary for VALO® Grand

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.

I. Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person: Ms. Marie Hess
Title: Sr. Regulatory Affairs Associate
Telephone: 801-553-4610
FAX: 801-553-4609

Date Summary Prepared: 12 July 2016

II. Name of the Device

Trade Name: VALO® Grand
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 is a battery operated, visible light activator for polymerization of dental resins of all photo-initiated dental materials. The VALO® Grand version functions the same as the predicate, VALO® Cordless, K110582, as a professional hand-held, LED-based, visible light curing device. The modified device, VALO® Grand, 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/cm^2. 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 for better ergonomics, and the middle power mode setting has been changed from 1400 to 1600 mW/cm^2, which makes it more central between the Standard and Xtra Power modes.

IV. Indications for Use: The VALO® Grand is a source of illumination for curing photo-activated dental restorative materials and adhesives.

V. Predicate Device: The predicate device is VALO® Cordless, cleared under 510(k) K110582.

VI. Indication of Risk Analysis Method:

Risk Analysis was performed on VALO® Grand utilizing processes based on ISO 14971:2012. Risks associated to patient safety and product efficacy for VALO® Grand have been identified, assessed, and controlled to level that is as low as currently feasible. Any remaining residual risks are not considered to be hazardous to patients, customers, and/or end users. Ultradent considers VALO® Grand to be substantially equivalent in its intended use as compared to the predicate device.

VII. Comparison of Technological Characteristics

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

Substantial equivalence comparison table:

Descriptive Information	**Device: VALO® Grand dental curing light**	**Predicate: VALO® Cordless dental curing light (K110582)**
Intended 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.
Intended User	Dentist or dental professional	Dentist or dental professional
Power source	**Batteries:** Lithium Iron Phosphate (LiFePO4) RCR123A with a working voltage of: 3.2VDC. Their safety ratings: CE, RoHS, WEEE **Power Charger**: 3.6VDC Lithium Ion Phosphate smart battery charger **AC Power Supply**: Connects to charger, wall powered. Output; 12VDC, 500mA. Input: 100VAC - 240VAC with adapters for international capability. Ratings: Medical Grade, (UL, CE, RoHS, WEEE) Cord: 6 ft (1.8m), 2.5mm DC connector **Power On Button:** Located on the handle of the wand, front and back side	**Batteries:** Lithium Iron Phosphate (LiFePO4) RCR123A with a working voltage of: 3.2VDC. Their safety ratings: CE, RoHS, WEEE **Power Charger**: 3.6VDC Lithium Ion Phosphate smart battery charger **AC Power Supply**: Connects to charger, wall powered. Output; 12VDC, 500mA. Input: 100VAC - 240VAC with adapters for international capability. Ratings: Medical Grade, (UL, CE, RoHS, WEEE) Cord: 6 ft (1.8m), 2.5mm DC connector **Power On Button**: Located on the handle of the wand, back side only
Operational modes	Standard Power Mode: 1000 mW/cm^2 High Power Plus Mode: 1600mW/cm^2 Xtra Power Mode: 3200mW/cm^2 Device indicates illumination time selection Device indicates time and time selection	Standard Power Mode: 1000 mW/cm^2 High Power Mode: 1400mW/cm^2 Xtra Power Mode: 3200mW/cm^2 Device indicates illumination time selection Device indicates time and time selection

Descriptive Information	Device: VALO® Grand dental curing light	Predicate: VALO® Cordless dental curing light (K110582)
Light source	LED light, blue and violet wavelengths 12mm light head diameter	LED light, blue and violet wavelengths 10 mm light head diameter
Accessories	Barrier Sleeve VALO®, VALO® Grand Light Shield	Barrier Sleeve VALO®, VALO® Cordless Light Shield
Composition of Materials	Aluminum, anodized black	Aluminum, anodized various colors
Parameters of Disinfection	Chemical disinfection with approved cleaning/sanitizing agents: Cavicide products Isopropyl alcohol Ethyl alcohol based cleaners Lysol disinfectant (alcohol-based only)	Chemical disinfection with approved cleaning/sanitizing agents: Cavicide products Isopropyl alcohol Ethyl alcohol based cleaners Lysol disinfectant (alcohol-based only)
Usability/Ergonomics	3 buttons – 2 power, 1 mode select	2 buttons – 1 power, 1 mode select

VALO® Grand is a similar device to the predicate, manufactured with identical materials and using the same energy source. VALO® Grand is used and cleaned in the same way by the same type of users. The differences between VALO® Grand and the predicate are the light head diameter (12 mm vs. 10 mm), the middle power mode (1600 mW/cm^2 vs. 1400 mW/cm^2), and the addition of a second power button. These differences do not impact safety or performance as described below, and therefore do not render the device not substantially equivalent.

VALO® Grand has been designed and tested according to the FDA Guidance Document Dental Curing Lights – Premarket Notification [510(k)]. Verification activities included curing hardness, depth of cure per ADA Specification No. 48, maximum light intensity measurements at 2 mm for all power modes, spectral irradiance plots of all power modes, and representative user testing. Biocompatibility and electrical safety/EMI testing were not performed on the new device, as there were no changes from the predicate that impacted conformance to these standards.

Based on the results of verification testing, the differences in technological characteristics did not raise different questions of safety or performance of the new device when tested against the predicate according to the FDA Guidance Document, Guidance for Industry and FDA Staff: Dental Curing Lights – Premarket Notification [510(k)] Submissions. Therefore, the VALO Grand is substantially equivalent to the predicate.