March 1, 2021

Ultradent Products, Inc
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K210550
Trade/Device Name: VALO Grand Corded and Accessory Lenses
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet activator for polymerization
Regulatory Class: Class II
Product Code: EBZ,EAQ, PEQ
Dated: February 19, 2021
Received: February 25, 2021

Dear Dave Yungvirt:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210550

Device Name
VALO Grand Corded and Accessory Lenses

Indications for Use *(Describe)*

VALO Grand Corded:
Source of illumination for curing photo-activated dental restorative materials and adhesives.

VALO Accessory Lenses:
The VALO Accessory Lenses are multiple-use accessory lenses intended to provide illumination to aid in visualization during oral procedures and augment the VALO family of curing lights, which are a source of illumination for curing photo-activated dental restorative materials and adhesives. VALO Accessory Lenses are not intended for complete cure of photo-activated 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.

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K210550

Section 5: 510(k) Summary

This summary of substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92 for VALO™ Grand Corded and Accessory Lenses.

I. Applicant's Name and Address

Ultradent Product, Inc.
505 West Ultradent Drive (10200 South)
South Jordan, UT 84095

Contact Person:	Mr. Adam Black
Title:	Regulatory Affairs Manager
Telephone:	801-553-4425
Fax:	801-553-4609

Date Summary Prepared: 12 February 2021

II. Name of the Device

Device:	Dental Curing Light
Trade/Device Name:	VALO™ Grand Corded and Accessory Lenses
Review Panel:	Dental
Regulation Number:	21 CFR 872.6070
Device Class:	Class II
Classification Product Code:	EBZ
Subsequent Product Code:	EAQ

III. Device Description

VALO™ Grand Corded:
With its broadband spectrum, VALO Grand Corded is designed to polymerize all light cured products in the wavelength range of 385-515nm per ISO 10650.
VALO has a medical grade, international power supply and is suitable for power outlets from 100 to 240 volts. The handpiece is designed to rest in a standard dental unit bracket or can be custom mounted using the bracket included with the kit.

Accessory Lenses:

- PointCure™ Lens
  - Augments the VALO curing light to polymerize composite through a translucent prosthetic.
- ProxiCure™ Ball Lens
  - Augments the VALO curing light to polymerize composite and help shape contact area matrix of an interproximal restoration.

- TransLume™ Green Lens
  - Augments the VALO curing light to aid in visualization by providing longer wavelength light to transilluminate teeth and dental prostheses.
- Black Light Lens
  - Augments the VALO curing light to provide aid in visualization of fluorescing chemicals in dental resins.
- Interproximal Lens
  - Augments the VALO curing light to aid in visualization of teeth and dental prostheses.
- White Light Lens
  - Augments the VALO curing light to provide a visual aid for accurate color/shade comparison or whenever natural light is needed.

IV. Statement of Intended Use

VALO Grand Corded:
Source of illumination for curing photo-activated dental restorative materials and adhesives.

VALO Accessory Lenses:
The VALO Accessory Lenses are multiple-use accessory lenses intended to provide illumination to aid in visualization during oral procedures and augment the VALO family of curing lights, which are a source of illumination for curing photo-activated dental restorative materials and adhesives. VALO Accessory Lenses are not intended for complete cure of photo-activated materials and adhesives.

V. Predicate Device

VALO Grand Corded and Accessory Lenses identified primary predicate: K190627 – VALO™ Grand Corded by Ultradent Products, Inc and secondary predicate: K101140 – FUSION-DOE by DentLight Inc.

VII. Comparison of Technological Characteristics

Predicate technological comparison:

The technology, delivery, and intended use of VALO™ Grand Corded and Accessory Lenses are substantially equivalent to the identified predicate devices as outlined in Table 5-1:

Table 5-1: VALO™ Grand Corded and Accessory Lenses substantial equivalence comparison

Descriptive Information	Device: VALO™ Grand Corded and Accessory Lenses	Primary Predicate: VALO™ Grand Corded (K190627)	Secondary Predicate: Dentlight Oral Exam Light Kit ("DOE") (K101140)
Product Code/ Classification	EBZ, EAQ – Class II	EBZ – Class II	EAQ – Class II
Indications for Use	**VALO Grand Corded**: The source of illumination for curing photo-activated dental restorative materials and adhesives. **Accessory Lenses**: The VALO Accessory Lenses are multiple-use accessory lenses intended to provide illumination to aid in visualization during oral procedures and augment the VALO family of curing lights, which are a source of illumination for curing photo-activated dental restorative materials and adhesives. VALO Accessory Lenses are not intended for complete cure of photo-activated materials and adhesives.	The source of illumination for curing photo-activated dental restorative materials and adhesives.	Dentlight Oral Exam Light Kit is indicated to be used by a dentist and physician for illumination to aid in visualization during oral procedures and an adjunct to enhance the visualization for oral examination of mucosal abnormalities and oral lesions
Intended User	Dentist or dental professional	Dentist or dental professional	Dentist or dental professional
Device Design: Power Source	**AC Power Supply:** Wall powered.	**AC Power Supply:** Wall powered.	Rechargeable Li-Ion batteries

	Output: 9VDC, 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 and front side UL Approved	Output: 9VDC, 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 and front side UL Approved	
Device Design: Operational Modes (Curing EBZ)	**VALO Grand Corded:** *Standard Power Mode: 1000 mW/cm^2 *High Power Plus Mode: 1600mW/cm^2 Xtra Power Mode: 3200mW/cm^2 *as measured by Demetron **Accessory Lenses:** ≥800 mW/cm^2 (PointCure – Recommened with High Power Mode) (ProxiCure – Recommended with mode suitable for material)	*Standard Power Mode: 1000 mW/cm^2 *High Power Plus Mode: 1600mW/cm^2 Xtra Power Mode: 3200mW/cm^2 *as measured by Demetron	N/A
Device Design: **Operational Modes (Diagnostic EAQ)**	**Accessory Lenses:** ≥25 mW/cm^2, ≤420 nm wavelength (Black Light Lens – Recommended with Standard Curing mode) ≥1,000 lx luminescence, 5,000-6,000 K color temperature, ≥85 CRI (White Light Lens – Recommended with Standard Curing mode) ≥15,000 lx luminescence, 500-570nm peak wavelengths (TransLume Green Lens – Recommended with Standard Curing mode)	N/A	**Violet or Blacklight:** 395 – 420 nm peak wavelength, ≥25 mW/cm^2* (Can be used in either mode) **White light:** ≥1,000 lx luminescence*, 5,000 – 6,000 K color temperature*, ≥65 CRI* (Can be used in either mode) *According to Manufacturer marketing material

	≥15,000 lx luminescence (Interproximal Lens – Recommended with Standard Curing mode)		
Device Design: Light Source	LED light, blue and violet wavelengths 12mm head size	LED light, blue and violet wavelengths 12mm head size	High Power LED
Device Design: Accessories	Barrier Sleeve VALO™, Blue-Light Blocking Glasses (VALO™ Grand Corded) PointCure Lens, ProxiCure Ball Lens, Translume Green Lens, Black Light Lens, Inter-proximal Lens, White Light Lens	Barrier Sleeve VALO™, Blue Light Blocking Glasses	-Light blocking safety glasses -Safety light blocking shields -Full accessories for fluorescent and transillumination oral exams -Tacking Tip -Curing Caps (3mm, 9mm, 13mm)
Composition of Materials	**VALO Grand Corded**: Aluminum, anodized black **Accessory Lenses**: Lens housing – Delrin Lens housing magnet – Neodymium Molded lens – Polymethylpentene TPX RT18 (PointCure, ProxiCure, TransLume Green, Interproximal) Black Light Filter – Glass White Light Filter – Type 2 phosphor	Aluminum, anodized black	Solid aircraft aluminum
Technical Specifications: Light Intensity	**VALO Grand Corded:** Standard: 900 mW/cm^2 High: 1,500 mW/ cm^2 Xtra: 2,100 mW/ cm^2 As measured by traceable Gigahertz spectrum analyzer **Accessory Lenses:**	Standard: 900 mW/cm^2 High: 1,500 mW/ cm^2 Xtra: 2,100 mW/ cm^2 As measured by traceable Gigahertz spectrum analyzer	**Curing Mode:** Pulse Mode: 2,000 mW/cm^2 Plasma Mode: 4,000 mW/ cm^2 **Violet Light Head:**

	≥800 mW/cm^2 (PointCure/ProxiCure) ≥25 mW/cm^2, ≤420 nm wavelength (Black Light Lens) ≥1,000 lx luminescence, 5,000-6,000 K color temperature, ≥85 CRI (White Light Lens) ≥15,000 lx luminescence, 500-570nm peak wavelengths (TransLume Green Lens) ≥15,000 lx luminescence (Interproximal Lens)		≥25 mW/cm^2* (Can be used in either mode) **White Light Head:** ≥1,000 lx luminescence* *According to Manufacturer marketing material
Technical Specifications: Peak Wavelength	**VALO Grand Corded:** Nominal values: 395-415nm and 440-480nm **Accessory Lenses:** All lenses match the curing lights peak wavelengths except: ≤420 nm wavelength (Black Light Lens), 500-570nm peak wavelengths (TransLume Green Lens)	Nominal values: 395-415nm and 440-480nm	Nominal values for curing light source and White Light Head: 440-480nm **Violet Light Head**: 395-420nm
Technical Specifications: Depth of Cure	2mm	2mm	2mm
Recognized Standards	ISO 10650:2018 IEC 80601-2-60:2019 ISO 14971:2007/(R)2010 IEC 62366-1:2015 ISO 10993-1:2018	ISO 10650:2015 IEC 80601-2-60:2012 IEC 60601-1 Ed. 3.1 ISO 14971:2007/(R)2010 IEC 62366-1:2015	ADA 48:2004 ISO 10650:2007 IEC 60601-1:2007 ISO 14971:2007
Parameters of Disinfection	**VALO Grand Corded:** Acceptable Cleaners - Lysol Brand III Disinfectant Spray (Recommended) Cavicide products (non-bleach)	Acceptable Cleaners: Lysol Brand III Disinfectant Spray (Recommended) Cavicide products (non-bleach) Isopropyl alcohol	Acceptable Cleaners: Lysol Brand III Disinfectant Spray (Recommended) Cavicide products (non-bleach) Isopropyl alcohol

	Isopropyl alcohol Ethyl alcohol-based cleaners Lysol Concentrate (alcohol-based only) **Accessory Lenses:** Cleaners – Henry Schein General Purpose Cleaner or equivalent product Disinfectant – Cidex® OPA Solution or equivalent product	Ethyl alcohol-based cleaners Lysol Concentrate (alcohol-based only)	Ethyl alcohol-based cleaners Lysol Concentrate (alcohol-based only)

As outlined in the comparison tables above, the VALO™ Grand Corded and Accessory Lenses are similar to the identified primary and secondary predicate devices with respect to intended use, power sources, light sources, principal of operation, intended user, and biocompatibility.

As this submission is to declare a significant change of introducing new accessories to a previously cleared device, the testing completed to demonstrate equivalence with the predicate included compatibility and functionality with the proposed new accessories. These tests show that the proposed VALO™ Accessory Lenses supplement the use of parent device of VALO™ Grand Corded. The proposed VALO™ Accessory Lenses supplement the VALO™ Grand Corded curing light as outlined above.

Device design validation and verification activities have been performed to FDA Guidance Document Dental Curing Lights – Premarket Notification [510(k)] and recognized standards and via internal testing protocols.

Non-clinical tests performed to establish substantial equivalence to identified predicate devices included radiant exitance and emission spectrum testing according to ISO 10650:2018, illuminance and color temperature testing, beam profile testing, duty cycle testing, and disinfection validation testing.

Conclusion: Based on these comparisons to the predicate device, we believe that VALO™ Grand Corded and Accessory Lenses are substantially equivalent to the predicate devices, in that they augment the use of the already cleared predicate, and do not raise new concerns of safety or efficacy.