February 22, 2022

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

Re: K220471
Trade/Device Name: VALO X, VALO X 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 16, 2022
Received: February 18, 2022

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 and
ENT 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)*
K220471

Device Name
VALO X; VALO X Accessory Lenses

Indications for Use *(Describe)*
VALO X curing light is a source of illumination for curing photo-activated dental restorative materials and adhesives. It is also intended to provide illumination to aid in visualization during oral procedures. VALO X curing light accessory/ diffusor 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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K220471

510(k) Summary

This summary of substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92 for VALO™ X and VALO™ X 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: 09 February 2022

II. Name of the Device

Device: Dental Curing Light
Trade/Device Name: VALO™ X; VALO™ X Accessory Lenses
Review Panel: Dental
Regulation Number: 21 CFR 872.6070
Device Class: Class II
Classification Product Code: EBZ
Subsequent Product Code: EAQ, PEQ

III. Device Description

VALO™ X:
With its broadband spectrum, VALO™ X curing light is designed to polymerize all light-cured products in the wavelength range of 380–515 nm per ISO 10650:2018.
The VALO X curing light can be used in a corded or cordless configuration using the Ultradent VALO rechargeable batteries or provided VALO X cord adapter. The curing light is designed to rest in a standard dental unit bracket or can be custom-mounted using the VALO surface mounting bracket included with the kit.

VALO™ X Accessory Lenses:

Accessory	Mode	Description
PointCure Lens	Curing Mode	Augments the VALO X curing light to polymerize composite through a translucent prosthetic.

ProxiCure Ball	Curing Mode	Augments the VALO X curing light to polymerize composite and help shape contact area matrix of an interproximal restoration.
Diffuser Lens	White Light Diagnostic Aid Mode	Augments the VALO X curing light to provide a visual aid for accurate color/shade comparison or whenever natural light is needed.
	Black Light Diagnostic Aid Mode	Augments the VALO X curing light to provide visualization of fluorescing chemicals in dental resins.
Interproximal Lens	White Light Diagnostic Aid Mode	Augments the VALO X curing light in visualization of teeth and dental prostheses.
Translume	Curing or Diagnostic Aid Modes	Augments the VALO X curing light in visualization by providing longer wavelength light to transilluminate teeth and dental prostheses.

IV. Statement of Intended Use

VALO X curing light is a source of illumination for curing photo-activated dental restorative materials and adhesives. It is also intended to provide illumination to aid in visualization during oral procedures. VALO X curing light accessory/diffusor lenses are not intended for complete cure of photo-activated materials and adhesives.

V. Predicate Device

VALO X and VALO X Accessory Lenses identified predicate device: K210550 – VALO™ Grand Corded and Accessory Lenses by Ultradent Products.

VI. Comparison of Technological Characteristics

Predicate technological comparison:

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

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

Descriptive Information	Devices: VALO™ X; VALO™ X Accessory Lenses	Predicate: VALO™ Grand Corded and Accessory Lenses (K210550)	Differences
Product Code/ Classification	EBZ, EAQ, PEQ – Class II	EBZ, EAQ, PEQ – Class II	Identical
Indications for Use	VALO X curing light is a source of illumination for curing photo-activated dental restorative materials and adhesives. It is also intended to provide illumination to aid in visualization during oral procedures. VALO X curing light accessory/diffusor lenses are not intended for complete cure of photo-activated materials and adhesives.	**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.	Similar
Intended User	Dentist or dental professional	Dentist or dental professional	Identical
Device Design: Power Source	VALO X curing light can be powered by an AC power supply or rechargeable batteries. **AC Power Supply:** Wall powered.	**AC Power Supply:** Wall powered. 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	Subject device can be used in a cordless mode with batteries or a corded mode with an AC power supply. Both power supply options

	Output: 9VDC, 2.0A. Input: 100VAC - 240VAC, 50-60 Hz with adapters for international capability. Ratings: Medical Grade, (CE, RoHS, REACH) Cord: 6 ft (1.8m), 2.5mm DC connector **Battery Power:** 1IMR14/65 3.7V 900mAh 3.33 Wh Li-Ion rechargeable battery pack **Power On Button**: Located on the handle of the wand, back side and front side	**Power On Button**: Located on the handle of the wand, back side and front side UL Approved	result in the same light output and device performance. Both the batteries and power supply have certifications to applicable electrical safety standards on their own. The subject device was also evaluated for electrical safety in both the corded and cordless configurations.
Device Design: Operational Modes (Curing EBZ)	**VALO X:** Standard Power Mode: 1,100 mW/cm^2 Xtra Power Mode: 2,200mW/cm^2 **VALO X Accessory Lenses:** ≥800 mW/cm^2 (PointCure – Recommened with High Power Mode) (ProxiCure – Recommended with mode suitable for material)	**VALO Grand Corded:** Standard Power Mode: 900 mW/cm^2 High Power Plus Mode: 1500mW/cm^2 Xtra Power Mode: 2100mW/cm^2 **Accessory Lenses:** ≥800 mW/cm^2 (PointCure – Recommened with High Power Mode) (ProxiCure – Recommended with mode suitable for material)	Removal of one curing mode to provide two simplistic curing modes for clinical use.
Device Design: **Operational Modes (Diagnostic EAQ, PEQ)**	**VALO X Accessory Lenses:** ≥25 mW/cm^2, ≤420 nm wavelength (Diffuser Lens – Black Light Diagnostic Aid Mode) ≥1,000 lx luminescence, 3,800-6,500 K color temperature, ≥75 CRI (Diffuser Lens – White Light Diagnostic Aid Mode)	**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)	Similar

	≥15,000 lx luminescence (Interproximal Lens – Recommended with Standard Curing mode) ≥500 nm wavelength (Translume Lens, any mode)	≥15,000 lx luminescence, 500-570nm peak wavelengths (TransLume Green Lens – Recommended with Standard Curing mode) ≥15,000 lx luminescence (Interproximal Lens – Recommended with Standard Curing mode)	
Device Design: Light Source	LED light, blue and violet wavelengths (Curing mode) LED light, violet or white wavelengths (Diagnostic mode) 12.5mm head size	LED light, blue and violet wavelengths 12mm head size	Additional white LED source was added for the White Light Diagnostic Aid Mode
Device Design: Accessories	-Barrier Sleeve VALO™, -Blue-Light Blocking Light Shield -PointCure Lens, ProxiCure Ball Lens, Translume Lens, Diffuser Lens, Inter-proximal Lens,	-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	Blue-Light blocking light shield is used in place of blue-light blocking glasses
Composition of Materials	**VALO X**: Aluminum, anodized black **VALO X Accessory Lenses**: Lens housing – Acetal Lens housing magnet – Neodymium Molded lens – Polymethylpentene TPX RT18 (PointCure, ProxiCure, TransLume Green, Interproximal) Diffuser Lens – Semi-Opaque White Glass	**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	Similar
Technical Specifications: Light Intensity	**VALO X:** Standard Power Mode: 1,100 mW/cm^2 Xtra Power Mode: 2,200mW/cm^2	**VALO Grand Corded:** Standard: 900 mW/cm^2 High: 1,500 mW/ cm^2	The slight difference in radiant exitance values

	As measured by traceable Gigahertz spectrum analyzer **VALO X Accessory Lenses:** ≥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) ≥500nm peak wavelengths (TransLume Green Lens) ≥15,000 lx luminescence (Interproximal Lens)	Xtra: 2,100 mW/ cm^2 As measured by traceable Gigahertz spectrum analyzer **Accessory Lenses:** ≥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)	is within the applied ISO 10650 standard.
Technical Specifications: Peak Wavelength	**VALO X:** Nominal values: 380-420nm and 420-515nm **VALO X Accessory Lenses:** All lenses match the curing lights peak wavelengths except: ≤420 nm wavelength (Diffuser Lens in Black Light Diagnostic Mode) ≥500 nm peak wavelength (Translume Lens, any mode)	**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)	Similar
Technical Specifications: Depth of Cure	2mm	2mm	Identical
Recognized Standards	ISO 10650:2018 IEC 80601-2-60:2019 ISO 14971:2019	ISO 10650:2018 IEC 80601-2-60:2019 ISO 14971:2007/(R)2010	The additional standards used during the development of the

	IEC 62366-1:2015 ISO 10993-1:2018 IEC 60601-1:2012 IEC 62471:2006	IEC 62366-1:2015 ISO 10993-1:2018	product reflect the standards applicable for the curing light alone. As the predicate submission, K210550, aimed at adding the additional VALO Accessory Lenses alone to a previously cleared VALO Grand Corded, K190627, these standards were not included in the submission but are currently applied to VALO Grand Corded.
Parameters of Disinfection	**VALO X:** Disinfectant: 70% isopropyl alcohol (IPA) **VALO X Accessory Lenses:** Cleaners – Henry Schein General Purpose Cleaner or equivalent product Disinfectant – Cidex® OPA Solution or equivalent product	**VALO Grand Corded:** Acceptable Cleaners - Lysol Brand III Disinfectant Spray (Recommended) Cavicide products (non-bleach) 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	Validated disinfectant is used in place of acceptable cleaners

User Interface	VALO X has minimal user interface items, two buttons with visual indicators and an accelerometer function allowing mode changes by a drum tap and wave motion.	VALO Grand Corded has a moderate user interface system. On the device itself there are three buttons and a visual indicator system.	Both the subject and predicate devices use different button presses to control functions, audible cues to acknowledge mode change, and indicator lights to identify current mode selected and other state/ functions. The addition of the accelerometer function to the subject device aims to enhance the user interface by allowing a simplified method to change modes.

As outlined in the comparison tables above, VALO™ X and VALO™ X Accessory Lenses are similar to the identified predicate device with respect to intended use, intended user, materials, light intensity, depth of cure, utilized consensus standards, peak wavelength and biocompatibility.

Primary differences between the subject device and predicate device are the option of using VALO X by means of batteries (cordless version) or AC power supply (corded version), the different operating modes (two curing modes and two diagnostic modes), the use of a blue-light blocking shield in place of blue-light blocking glasses, updated user interface with fewer buttons and the addition of an accelerometer function, the addition of a fourth white-wavelength LED, and the reliance on a validated disinfectant process rather than a list of acceptable cleaners.

VII. Performance Data

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. Software verification and validation of the device were conducted in accordance with the FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Non-clinical tests performed to establish substantial equivalence to the identified predicate device included radiant exitance, illuminance and color temperature, beam profile, duty cycle, EMC, electromagnetic disturbance, photobiological safety and disinfection validation testing. See the table below for standards used during non-clinical testing.

ISO 10650:2018	Dentistry – Powered polymerization activators
IEC 80601-2-60:2019	Particular requirements for basic safety and essential performance of dental equipment
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within risk management process
IEC 60601-1:2012	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2014	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 62471:2006	Photobiological safety of lamps and lamp systems

Conclusion: Based on these comparisons to the predicate device, we believe that VALO™ X and VALO™ X Accessory Lenses are substantially equivalent to the predicate device, in that they achieve the same intended use by similar technologies that do not raise new concerns of safety or efficacy.