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

Inter-Med / Vista Dental Products
Alex Johnson
Sr. Product Development Engineer
2200 South St. Ste. A
Racine, Wisconsin 53404

June 8, 2017

Re: K170101
Trade/Device Name: Valiant Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: May 5, 2017
Received: May 8, 2017

Dear Alex Johnson:

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,

Mary S. Runner -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170101

Device Name
Valiant Curing Light

Indications for Use *(Describe)*
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.

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510(k) Summary
for
Valiant Curing Light

1. Applicant

Submitter's Name: Alex Johnson, MSc
John Baeten, MSc

Date Summary Prepared: June 7, 2017

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Contact Person: Alex Johnson, MSc

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2. Device Name

Proprietary Name: Valiant Curing Light
Common Name: Ultraviolet activator for polymerization
Classification Name: Ultraviolet activator for polymerization (21 CFR 872.6070, Product Code EBZ)
Device Class: 2

3. Primary Predicate Device

Valo Cordless (K110582) by Ultradent Products

- **Common Name**: Ultraviolet activator for polymerization
- **Classification Name**: Ultraviolet activator for polymerization (21 CFR 872.6070)
- **Product Code**: EBZ
- **Device Class:** 2

Reference Device

Sirius Max (K152936) by National Dental, Inc.

- **Common Name**: Ultraviolet activator for polymerization
- **Classification Name**: Ultraviolet activator for polymerization (21 CFR 872.6070)
- **Product Code**: EBZ
- **Device Class:** 2

4. Device Description

The Valiant Curing Light is a visible light activator for polymerization of dental materials and adhesives, such as dental resins and composites. The Valiant Curing Light is composed of a cordless handpiece, a charging base, disposable barrier sleeves, a light attenuating shield, and an instruction for use. The cordless handpiece is made of medical grade aluminum, electronic elements, glass lenses, and medical grade plastic elements. A plastic rotation switch provides an interface to switch between various modes of the cordless handpiece. Once a mode is selected, an ON/OFF button activates and executes the selected mode. The unit is battery operated and contains a removable and rechargeable Li ion battery. The charging base allows for placement and inductive charging of the handpiece when not in use. The light attenuating shield absorbs emitted light from the cordless handpiece to minimize ocular radiation to the patient and user. The Valiant Curing Light is provided non-sterile. Disposable barrier sleeves (510(k) number K132953, TIDI Shield, Model 21102, by TIDI Products) assist in mitigating patient-to-patient contamination; additionally, the handpiece, charging base and light attenuating shield can withstand common surface disinfectants. Also included in the Valiant Curing Light is an instructions for use. The instructions for use details the function and four independently operable settings of the device: 1) standard curing mode, 2) ramp curing mode, 3) boost curing mode, and 4) white light mode (visualizing of dental anatomy). The white light mode can be used for intraoral illumination to aid in the visualization of dental anatomy (i.e. equivalent to a class I dental operating light, CFR 872.4630). The curing light modes 1-3 provide broad spectrum blue light (400 – 500nm, with peaks at 410nm and 475nm) to cure a variety of dental restorative materials and adhesives utilizing the most common photoinitiators (CQ and PPD). The white light mode 4 provides an aid for illuminating dental anatomy.

This is the only 510(k) for this medical device, no prior 510(k)s have been submitted.

5. Intended Use / Indication for Use

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

6. Technological Characteristics and Substantial Equivalence

	Predicate Device: Valo Cordless (Ultradent Products)	**Valiant Curing Light (Inter-Med / Vista Dental Products)**	**Reference Device: Sirius Max (National Dental, Inc.)**
Common name	Activator, ultraviolet for polymerization	Activator, ultraviolet for polymerization	Activator, ultraviolet for polymerization

	Predicate Device: Valo Cordless (Ultradent Products)			Valiant Curing Light (Inter-Med / Vista Dental Products)			Reference Device: Sirius Max (National Dental, Inc.)		
FDA classification name and number	872.6070 Ultraviolet activator for polymerization			872.6070 Ultraviolet activator for polymerization			872.6070 Ultraviolet activator for polymerization		
510(k) number	K110582			K170101 (pending)			K152936		
Product code	EBZ			EBZ			EBZ		
Indication for use / intended use	Source of illumination for curing photo-activated dental restorative materials and adhesives.			Source of illumination for curing photo-activated dental restorative materials and adhesives.			The Sirius Max Diode Curing Light is intended for use as a source of illumination for photo initiated curing and/or activation/polymerization of dental restorative materials and adhesives.		
Where used	Dental offices and health care offices			Dental offices and health care offices			Dental offices and health care offices		
Target population	Health care professionals			Health care professionals			Health care professionals		
Anatomical site	Oral cavity			Oral cavity			Oral cavity		
Light source	4 broad blue LEDs for photo-initiated curing of dental materials			4 broad blue LEDs for photo-initiated curing of dental materials 1 white light LED for transillumination			1 broad blue LED for photo-initiated curing of dental materials 1 white light LED for transillumination		
Curing settings (light intensity and pulse characteristics)	Mode	Power (mW/cm^2)	Duration (s)	Mode	Power (mW/cm^2)	Duration (s)	Mode	Power (mW/cm^2)	Duration (s)
	Standard	1000	5, 10, 15, 20	Standard	1200	20 (beep at 10s)	Normal	1200	10, 20
				Ramp	1200	20 (beep at	Soft Start	1400	15

	Predicate Device: Valo Cordless (Ultradent Products)			Valiant Curing Light (Inter-Med / Vista Dental Products)			Reference Device: Sirius Max (National Dental, Inc.)		
						10s)			
	High power	1400	1, 2, 3, 4	Boost	1700	5	High Power	1300	5
	Xtra power	3200	3	N/A	N/A	N/A	Pulse	1400	5, 10
							Xtra Power	3000	1, 3
							Orthodontics	1400	10x3
Curing wavelengths	Broad spectrum blue light (395nm-480nm) Peaks at 465nm and 400nm			Broad spectrum blue light (400nm-500nm) Peaks at 475nm and 410nm			Broad spectrum blue light (430nm-490nm) Peak at 460nm		
Cooling system	Convection cooled			Convection cooled			Convection cooled		
Materials	Aluminum body, glass lens, plastic controls / elements			Aluminum body, glass lens, plastic controls / elements			Aluminum body, glass lens, plastic controls / elements		
Sterility	Non sterile			Non sterile			Non sterile		
Radiation safety	Complies with ADA 48			Complies with ADA 48			Complies with ADA 48		
Electrical safety	IEC 60601-1			IEC 60601-1 IEC 62133			IEC 60601-1		

	Predicate Device: Valo Cordless (Ultradent Products)	Valiant Curing Light (Inter-Med / Vista Dental Products)	Reference Device: Sirius Max (National Dental, Inc.)
Standards met	IEC 60601-1 Complies with ADA 48	IEC 60601-1 IEC 62133 Complies with ADA 48 / ISO 10650-2 ISO 14971 ISO 10993-1 IEC 62471	IEC 60601-1 Complies with ADA 48

Similarities between the Valiant Curing Light and Valo Cordless

- The Valiant Curing Light has identical indications for use as the predicate device, the Valo Cordless.
- The Valiant Curing Light has the same mode of action as the predicate device, the Valo Cordless (i.e. photo-polymerization of monomers and oligomers to polymers via activation of photoinitiators).
- The Valiant Curing Light has equivalent performance characteristics as the predicate device (Valo Cordless) as both products use the same light source (LED).
- The Valiant Curing Light uses a combination of LEDs to activate CQ and TPO photoinitiators, similarly to the predicate device (Valo Cordless).
- The Valiant Curing Light is substantially equivalent to the predicate device (Valo Cordless) as both devices shown compliance with IEC 60601-1 and ADA 48 (i.e. ISO 10650-1).
- The Valiant Curing Light and the Valo Cordless are both equivalent in their design; both medical devices are Li-ion battery operated cordless devices with an aluminum body construction.

Differences between the Valiant Curing Light and Valo Cordless

- Although the Valiant Curing Light and Valo Cordless have different light intensity results and curing wavelengths, these differences do not raise any substantial equivalence concerns as the Valiant Curing Light and Valo Cordless curing dental materials equally
    - See DHF10018 - TR002: No statistical difference in microhardness was measured from the investigated dental materials post-cure using the Valiant Curing Light or Valo Cordless. Because the Valiant Curing Light has a lower optical power than the Valo, yet cures dental materials equivalently, safety of the Valiant Curing Light is further supported.
- The Valiant Curing Light and Valo Cordless have slightly different curing settings
    - The Valiant Curing Light provides standard, ramp, and boost curing modes while the Valo Cordless provides standard, high power, and xtra power modes.
    - The Valiant Curing Light was designed for simplicity, i.e. there is not an option to change the duration during the various curing modes.

  - This difference does not raise any substantial equivalence concerns as the Valiant Curing Light and Valo Cordless cure dental materials equally.
  - It should be noted that other 510(k) cleared dental curing lights also contain a ramp curing mode. Please reference Sirius Max Diode Curing Light 510(k) K152936, which utilizes a "soft start" mode where the optical power of curing LEDs is ramped over a set period of time. This product is only provided here for reference. Inter-Med / Vista Dental Products is not claiming substantial equivalence to the Sirius Max Diode Curing Light.
- The Valiant Curing Light contains a white light mode (white light LED) which is operated independently from the curing light LEDs; the Valo Cordless does not contain a white light mode option.
  - The white light can be used for intraoral illumination to aid in the visualization of dental anatomy.
  - This difference does not raise any substantial equivalence concerns as the Valiant Curing Light's white light mode is a class I dental operating light (CFR 872.4630).
  - It should be noted that other 510(k) cleared dental curing lights also contain a white light mode. Please reference Sirius Max Diode Curing Light 510(k) K152936 which includes a white light option for transillumination and visualization of dental anatomy. This product is only provided here for reference. Inter-Med / Vista Dental Products is not claiming substantial equivalence to the Sirius Max Diode Curing Light.
- The Valiant Curing Light and predicate curing light (Valo Cordless) share similar intended uses, technical characteristics, features, and specifications. The dental curing characteristics of Valiant Curing Light are statistically significantly similar to the cleared medical / predicate device: Valo Cordless (510(k) K110582). Therefore, the Valiant Curing Light is substantially equivalent to the predicate device.

Applicable Standards

- IEC 60601-1:2005 Medical electrical equipment Part 1: General requirements for basic safety and essential performance (3rd Edition)
- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests (4th Edition)
- IEC 62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications (2nd Edition)
- ADA48-2-2010 ANSI/ADA Standard No. 48-2 LED Curing Lights
- ISO 14971:2007 – Application of Risk Management to Medical Devices
- ISO 14971:2012 – Application of Risk Management to Medical Devices
- ISO 10993-1:2009 Biological Evaluation of Medical Devices Part 1 – Evaluation and Testing
- IEC 62741 Photobiological Safety of Lamps and Lamp Systems

7. Non-Clinical Performance Testing and Compliance

The following non-clinical tests were conducted to evaluate the functionality, performance, safety, and substantial equivalence of the Valiant Curing Light as suggested by the FDA's guidance for industry and FDA staff titled "Dental Curing Lights – Premarket Notification [510(k)] Submissions" issued on March 27, 2006:

- DHF 10018 – TR001 – Heat Generation Testing
  - Testing concluded that the Valiant Curing Light did not reach unsafe temperatures within typical use.
  - No hazard or warning statement is required in the products instructions for use.
- DHF 10018 – TR002 – Composite Hardness Testing
  - Testing concluded that both the Valo and Valiant Curing Lights cure dental composite effectively. Hardness measurements obtained from cured composite pucks using the two curing lights were statistically similar. Testing confirms that the Valiant Curing Light adequately cures dental composite to depths of 2mm. This testing verifies the Valiant's efficacy and supports Valiant's substantial equivalence to the Valo.
- DHF 10018 – TR003 – Wavelength Spectrum Testing
  - Testing verified that the spectrum emitted from the Valiant matches the design criteria. Comparison testing between the Valiant and Valo curing lights supports substantial equivalence as both curing lights emits nearly identical wavelength spectrums for curing dental materials.
- DHF 10018 – TR004 – Optical Power Testing
  - Testing verified that the Valiant's optical power matches the design criteria. Comparison testing between the Valiant and Valo curing lights supports substantial equivalence as the Valiant has identical or lower optical power results.
  - Additionally, the light attenuating shield was shown to block >99% of emitted optical power; thus, supporting safety and effectiveness of the Valiant's light attenuating shield.
- DHF 10018 – TR005 – Software Verification and Validation Testing
  - The Valiant Curing Light contains software that was developed in full compliance with the 2005 FDA Software Guidance (Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11th, 2005.
  - Testing verified that the Valiant's software functions properly.
- Electrical safety and electromagnetic compatibility testing
  - The Valiant Curing Light complies with IEC 60601-1 electrical safety and electromagnetic compatibility testing.

8. Clinical Performance Testing and Compliance

Clinical performance is not deemed necessary.

9. Conclusion

The Valiant Curing Light is substantially equivalent to Valo Cordless (K110582) in intended use and operation; both medical devices use LEDs as the source of light for curing dental materials. Benchtop testing supports substantial equivalence of the Valiant to the Valo Cordless.