August 14, 2020

Garrison Dental Solutions, LLC
% Michael Tomasovich
Senior Regulatory Specialist
Regulatory Affairs Associates, LLC
4761 Tara Court
West Bloomfield, Michigan 48323

Re: K200775
Trade/Device Name: LOOP LED Curing Light System
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: July 16, 2020
Received: July 21, 2020

Dear Michael Tomasovich:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200775

Device Name
LOOP LED Curing Light System

Indications for Use *(Describe)*
The LOOP 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.

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Section 02 510(k) Summary (K200775)

[as required by section 807.92(c)]

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. SUBMITTER

Submitted by:	Garrison Dental Solutions, LLC 150 DeWitt Lane Spring Lake, MI 49456 USA Phone: 1-616-842-2244 Fax: 1-616-842-2430 Email: ahull@garrisondental.com
Contact Person:	Michael Tomasovich, MS RAC Regulatory Affairs Associates, LLC 4761 Tara Court West Bloomfield, MI 48323 USA Phone: 1-734-788-3480 Fax: 1-313-557-4200 Email: mtomasovich@regaffairs.net
Date Prepared:	July 3, 2020

II. DEVICE

Trade Name:	LOOP™ LED Curing Light System
Common Name:	Activator, ultraviolet for polymerization
Model:	CLK01
Regulation:	21 CFR §872.6070
Regulatory Class:	II
Product Code:	EBZ
Classification Name:	Ultraviolet activator for polymerization
Review Panel:	Dental

III. PRIMARY PREDICATE DEVICE

Trade Name:	VALO Cordless
Manufacturer:	Ultradent Products, Inc.
Common Name:	Activator, ultraviolet for polymerization

Regulation: 21 CFR §872.6070
Regulatory Class: II
Product Code: EBZ
510k Number: K110582
Review Panel: Dental

IV. DEVICE DESCRIPTION

LOOP™ is a LED (Light Emitting Diode) light source for polymerization of dental materials for use by trained dental professionals. It is suitable for use with a broad range of light-cured dental materials including materials for restoratives such as light-cured and dual-cure cements, composites, bonding agents/adhesives, bases, liners, fissure sealants, temporaries, as well as luting materials for brackets and indirect restorations such as ceramic inlays. LOOP™ consists of a wireless handpiece and a charging base with an integrated calibration station. The device is a medical electrical device in accordance with IEC 60601-1-2.

LOOP™ features a patented coaxial feedback sensing system that measures the actual irradiance, which is the light power striking the targeted tooth. The feedback data allows LOOP™ to make corrective adjustments to the LED power output hundreds of times per second. This continual corrected "closed loop" operation ensures that the targeted surface of the restorative dental material receives the intended irradiance independent of operator-induced distance variations.

V. INDICATIONS FOR USE

The LOOP™ is a source of illumination for curing photo-activated dental restorative materials and adhesives.

VI. COMPARISON OF TECHNICAL CHARACTRISTICS WITH THE PREDICATE DEVICE

Name	LOOP LED Curing Light System	VALO Cordless Dental Curing Light (Primary Predicate)	Substantial Equivalence Assessment
510(k) Number	K200775	K110582	
Applicant	Garrison Dental Solutions	Ultradent Products	
Common Name	Activator, ultraviolet for polymerization	Activator, ultraviolet for polymerization	SE

Classification Name	Ultraviolet activator for polymerization	Ultraviolet activator for Polymerization	SE
Regulation	21 CFR 872.6070	21 CFR 872.6070	SE
Product Code	EBZ	EBZ	SE
Intended Use	The LOOP is a 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.	SE
Intended User	Dentist or dental professional	Dentist or dental professional	SE
Power source	**Batteries:** Litium Ion 18650 with a working voltage of 3.7 VDC	**Batteries:** Lithium Iron Phosphate (LiFePO4) RCR123A with a working voltage of 3.2 VDC	SE Note 1
	Safety rating: IEC 62133, RoHS, WEEE	Safety rating: CE, RoHS, WEEE	SE
	Power Charger: 4.2 VDC Lithium Ion smart battery charger	**Power Charger:** 3.6 VDC Lithium Iron Phosphate smart battery charger	SE Note 1
	AC Power Supply: Connects to charger, wall powered. Output: 5VDC, 2A Input: 100VAC - 240VAC with adapters for international capability	**AC Power Supply**: Connects to charger, wall powered. Output: 12 VDC, 500mA Input: 100VAC - 240VAC with adapters for international capability	SE Note 1
	Medical Grade: IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, RoHS, WEE	Medical Grade: UL, CE, RoHS, WEEE	SE Note 1
	Cord: 4ft (1.2m), 2.5mm DC connector	Cord: 6ft (1.8m), 2.5mm DC connector	SE Note 1
	Power On Button: Located on handle of wand	**Power On Button**: Located on handle of wand, back side only	SE
Operational Modes	Repeat Mode: 1000, 1500 and 2000 mW/cm2*	Standard Power Mode: 1000 mW/cm2	SE Note 2
	Direct Restorative Mode: 1000, 1200 and 1500 mW/cm2**	High Power Mode: 1400 mW/cm2*	SE Note 2
	Turbo Mode: 2000, 2500 and 3000 mW/cm2**	Xtra Power Mode: 3200 mW/CM2*	SE Note 2

	* Relative to lens surface ** Relative to the target surface	* Relative to lens surface	SE
	Device indicates illumination power and time selection	Device indicates power and time selection	SE
Light Source	LED light, blue and violet wavelengths (390-480nm) 9.7mm light head diameter	LED light, blue and violet wavelengths (395-480nm) 10mm light head diameter	SE Note 3
Accessories	LOOP Protective Barrier Sleeves, LOOP Protective Light Shield	Barrier Sleeve VALO, VALO Cordless Light Shield	SE
Composition of Materials	Aluminum, powder coated various colors	Aluminum, anodized various colors	SE Note 4
Sterility	Supplied Non-sterile	Supplied Non-sterile	SE
Parameters of Disinfection	Chemical disinfection with approved cleaning /sanitizing agents: Cavicide products (non-bleach) Isopropyl alcohol Lysol disinfectant (alcohol-based only) FD 366 (Durr Dental)	Chemical disinfection with approved cleaning /sanitizing agents: Cavicide products (non-bleach) Isopropyl alcohol Ethyl alcohol based cleaners Lysol disinfectant (alcohol-based only)	SE
Usability / Ergonomics	3 buttons: 1 cure power, 1 select mode, 1 time select	2 buttons: 1 cure power, 1 mode select	SE Note 5
Dimensions	Length 205.5mm (8.09in) Width 35.5mm (1.4in) Weight 190g (6.7oz)	Length 203mm (8in) Width 32.5mm (1.28in) Weight 190g (6.7oz)	SE
Storage and Transport Conditions	0 C to 40 C (32 F to 104 F) 0 to 85% RH Atmospheric Pressure: 500 hPa up to 1060 hPa	10 C to 40 C (50 F to 104 F) 10% to 95% RH Atmospheric Pressure: 500 hPa to 1060 hPa	SE
Warranty	3 Years	3 Years	SE

Note 1- Power Source

The power supply for both products is a battery source. While the LOOP utilizes a Lithium Ion battery and the VALO uses a Lithium Iron Phosphate battery, they are both rechargeable Lithium

cells that hold the same safety ratings. The difference in Voltage Direct Current (VDC) between the two cells is 0.5 which is attributed to the size of the cells and the charging capacity. Both cells have been proven compliant with IEC 60601-1 Electrical Safety testing.

Both Power Chargers are smart battery chargers and provide the appropriate VDC based upon the type of Lithium cell used. The rate or power of charge to the battery does not affect the safety and effectiveness of the device as both chargers are considered medical grade chargers accepting the same Volts Alternating Currents (VAC) input of 100-240VAC.

The power cords for the chargers are 4ft and 6ft respectively, and both are made of the same standard wiring with 2.5mm DC connectors. The differences in the lengths of the cords have no impact on the safety and effectiveness of the devices.

The differences associated with the power source have no impact on the safety and effectiveness. Accordingly, the power sources for the two products should be considered substantially equivalent.

Note 2 – Operational Modes

Both the LOOP and VALO products have three operational modes. The LOOP has an operational range from 1000 – 3000 mW/cm^2. The VALO has an operational range from 1000 – 3200 mW/cm^2. The minimum range of operation for the two products is the same. The LOOP has a maximum output operational mode that is 200 mW/cm^2 less than the VALO. Comparative testing was performed by Garrison Dental Solutions for evaluation of the published irradiance outputs for the purpose of establishing substantial equivalence. The findings of this comparative irradiance testing support substantial equivalence between the LOOP and VALO with respect to operational modes irradiance.

Note 3 – Light Source

Both the LOOP and VALO products possess an LED light source that produces blue and violet wavelengths. The LOOP has a wavelength range of 390-480nm while the VALO has a wavelength range of 395-480nm. The LOOP output is 5nm lower on the bottom end of the range. In both devices the lower wavelength LED is for the purpose of activating the Lucirin TPO photo-initiator that some resin based composites use. TPO's absorption spectrum is 380-425nm and more effective on the lower end of the wavelength spectrum. Both products will cure TPO composites similarly, with the LOOP being marginally more efficient.

The size of the light head for the LOOP is 9.7mm and the light head of the VALO is 10mm. The difference between the light head size is 0.3mm. While the difference is size is miniscule, the wavelength output range is the same as discussed above.

For purposes of light source the LOOP and VALO are substantially equivalent.

Note 4 – Composition of Materials

Both products are made of aluminum. The LOOP has a powder coating protective layer while the VALO has an anodized protective oxide layer coating. The type of coating applied to the aluminum has no impact on the safety and effectiveness of the device. As both products are made of aluminum they are substantially equivalent.

Note 5 – Usability / Egonomics

The LOOP has three buttons that can be used for selection: cure power, select mode, and time select. The VALO possesses two buttons: cure power and mode select. The LOOP has the same usability functions as the VALO but also provides the user with more product control by allowing a time selection. Since the LOOP has the same usability functions as the VALO it is substantially equivalent.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility Testing

Garrison Dental conducted cytotoxicity, hypersensitivity and reactivity biocompatibility testing because although the device does not come in contact with oral tissue on the chance that contact does occur Garrison confirmed that its product passes biocompatibility requirements.

The biocompatibility evaluation of the LOOP was conducted in accordance with ISO 10993-5:2009 Biological Evaluation of Medical Devices Part-5: Test for In Vitro Cytotoxicity and ISO 10993-10:2010 Biological Evaluation of Medical Devices Part-10: Test for Irritation and Skin Sensitization as recognized by FDA as standards 2-245 and 2-174, respectively. The battery of testing included the following Tests:

- Cytotoxicity – MEM Elution Test
- Maximization Test for Delayed-Type Hypersensitivity in Hartley Guinea Pigs
- Intracutaneous (Intradermal) Reactivity Test in New Zealand White Rabbits

Testing concluded that the test article did not have a cytotoxic effect, did not elicit sensitization reactions, and did not elicit biologically significant irritation reactions.

Electromagnetic Compatibility (EMC) and Electrical Safety

Electrical safety and EMC testing were conducted on the LOOP and the Lithium Ion battery. The system complies with the following standards:

- IEC 60601-1
- IEC 60601-2
- IEC 60601-1-6
- IEC 60601-1-11
- IEC 60101-2-57
- IEC 62133
- IEC 62471
- IEC 60601-1 Clause 8

Software Verification and Validation Testing

Software verification and validation testing were conducted. The software for the LOOP was considered as a "moderate" level of concern based on the determination that minor injury could result prior to mitigation of hazards due to software failure, and because a malfunction of or a latent design flaw could result in an erroneous diagnosis or a delay in delivery of appropriate medical case that would likely lead to minor injury.

Mechanical and Engineering Testing

- S-LED Design Verification and Plan Report
- Vibration and Shock Test (Wand & Charger)
- 3-Year Lifecycle Durability
- Long Term Battery Test
- Black Calibration Study using Different Materials
- Characterization of Curing Light Tips
- Upper Charger Base Rotation Measurement
- Chemical and Scratch Resistance Testing of Curing Light Cover
- Thermal Cycling of Capillary for Time Determination
- Evaluation of Lens Hardness
- Barrier Sleeve Reflectance Testing
- 1-Day Thermal / Humidity Testing While Functioning
- Reflectance Difference across Device Testing
- Barrier Sleeve Height Sensitivity Testing
- Irradiance Penetration Testing from Composites
- Touch Temperature Test
- Marc Light Collector Certification Trial
- Repeatability Testing – Changes in Device Behavior with Lens Debris

- Verification of Radiometric Function Performance
- Light Shield Testing for Light Blocking Effectiveness
- Moisture Ingress Assessment
- Water Ingress Simulation Test – Wand
- Beam Analysis
- Radiometric Evaluation – Barrier Sleeve Effect on Want
- Reflection Testing – Angled Surfaces
- In Vivo Usability – Turn on/off distances
- Verification and validation – Wand's Systems Function
- Centroid Correlation
- ISO 10650-2:2018 – Powered Polymerization Activators
- Reflectance Testing – Auto Start Distances on Human Tissue
- Liquid Ingress Testing – Charger
- Auto Start Testing – Various Dental Materials
- Predicate Irradiance Comparison
- Serviceability – Battery Replacement
- Mechanical Attribute Examination
- Chemical Resistance Testing
- Light Shield Fit Test
- VALO, G4 and LOOP Irradiance Comparison
- Charger Base Calibration Study
- Human Factor and Usability Engineering

Animal and Clinical Studies

No animal or clinical studies were conducted.

VIII. CONCLUSIONS

The VALO (predicate device) is cleared for the same indication for use/intended use under the same regulation and product code as the LOOP (primary device). The devices both operate using rechargeable batteries, are both hand-held dental curing lights, provide operational output sources within the same range, emit the same LED light in blue and violet wavelengths within the same ranges, have the same type of accessories, are both made of aluminum, are both supplied non-sterile and can be cleaned using the same types of products. Non-clinical testing and data support substantial equivalence and the hardware and software verification and validation demonstrate the LOOP LED Curing Light System should perform as intended in the specified use conditions. Direct comparative testing shows the LOOP performs as well or better than the VALO predicate device in all aspects. A determination for substantial equivalence should be found and the LOOP LED Curing Light System cleared for marketability.