



August 1, 2024

Garrison Dental Solutions, LLC
% Michael Tomasovich
Sr. Regulatory Specialist/Manager
Regulatory Affairs Associates, LLC
4761 Tara Court
West Bloomfield, Michigan 48323

Re: K241238

Trade/Device Name: LOOP™ LED Curing Light System (CLK01)

Regulation Number: 21 CFR 872.6070

Regulation Name: Ultraviolet Activator For Polymerization

Regulatory Class: Class II

Product Code: EBZ

Dated: May 2, 2024

Received: May 3, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
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

Indications for Use

510(k) Number (if known)

K241238

Device Name

LOOP™ LED Curing Light System

Indications for Use (Describe)

Indications for Use: 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 (K241238)** [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**

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Date Prepared: May 2, 2024

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. **Predicate Device (Primary Predicate)**

Trade Name: LOOP™ LED Curing Light System (rev H)
Manufacturer: Garrison Dental Solutions, LLC
Common Name: Activator, ultraviolet for polymerization
Model: CLK01
Regulation: 21 CFR §872.6070

Regulatory Class:	II
Product Code:	EBZ
510K Number:	K200775
Classification Name:	Ultraviolet activator for polymerization
Review Panel:	Dental

IV. Device Description

LOOP™ is a high-performance LED (Light Emitting Diode) light source for polymerization of dental materials used 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. Indication

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

VI. Comparison to Predicate Device

The proposed device, LOOP™ LED Curing Light System (rev K), is a source of illumination for curing photo-activated dental restorative materials and adhesives which has the same intended uses as the proposed predicate device, the LOOP™ LED Curing Light System (rev K, K200775).

Both devices are battery powered hand-held devices to be used by dentists or dental professionals that also come with AC power supply wall chargers. Power outputs for both devices range from 1000-3000 mW/cm². Both devices use LED light in blue and violet wavelengths with light head diameters of 9.7mm.

Both products come with protective barrier sleeves.

The predicate device has a housing made of cast aluminum. The current device has a housing made of injection molded plastic resin.

The current device has a setting which allows the dental professional (the user) to disable the “closed loop” functionality so that it operates like any other curing light. The predicate device does not allow “closed loop” to be disabled by the user.

Name	LOOP™ LED Curing Light System (Rev K)	LOOP™ LED Curing Light System (Rev H)	
510(k) Number	To be determined	K200775	
Applicant	Garrison Dental Solutions	Garrison Dental Solutions	
Common Name	Activator, ultraviolet for polymerization	Activator, ultraviolet for polymerization	Same
Classification Name	Ultraviolet activator for polymerization	Ultraviolet activator for polymerization	Same
Regulation	21 CFR §872.6070	21 CFR §872.6070	Same
Product Code	EBZ	EBZ	Same
Intended Use	The LOOP is a source of illumination for curing photo-activated dental restorative materials and adhesives.	The LOOP is a source of illumination for curing photo-activated dental restorative materials and adhesives.	Same
Intended User	Dentist or dental professional	Dentist or dental professional	Same
Power source	<p>Batteries: Lithium Ion 18650 with a working voltage of 3.7 VDC Safety rating: IEC 62133, RoHS, WEEE Power Charger: 4.2VDC Lithium Ion smart battery charger AC Power Supply: Connects to charger, wall powered. Output: 5VDC, 2A. Input: 100VAC – 240VAC with adapters for international capability. Ratings: Medical Grade, IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, CE, RoHS, WEEE Cord: 4 ft (1.2m), 2.5mm DC connector Power On Button: Located on the handle of wand</p>	<p>Batteries: Lithium Ion 18650 with a working voltage of 3.7 VDC Safety rating: IEC 62133, RoHS, WEEE Power Charger: 4.2VDC Lithium Ion smart battery charger AC Power Supply: Connects to charger, wall powered. Output: 5VDC, 2A. Input: 100VAC – 240VAC with adapters for international capability. Ratings: Medical Grade, IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, CE, RoHS, WEEE Cord: 4 ft (1.2m), 2.5mm DC connector Power On Button: Located on the handle of wand</p>	<p>Same</p> <p>Same</p> <p>Same</p>
Operational modes	<p>Open Loop Mode: 1000, 2000 and 3000 mW/cm² * Closed Loop Mode: 1000, 2000 and 3000 mW/cm² **</p>	<p>Repeat Mode: 1000, 1500 and 2000 mW/cm² * Direct Restorative Mode: 1000, 1200 and 1500 mW/cm² ** Turbo Mode: 2000, 2500 and 3000 mW/cm² **</p>	Substantially equivalent

Name	LOOP™ LED Curing Light System (Rev K)	LOOP™ LED Curing Light System (Rev H)	
	*Relative to lens surface **Relative to the target surface	*Relative to lens surface **Relative to the target surface	Same
	Device indicates mode, illumination power and time selection	Device indicates mode, illumination power and time selection	Same
Light source	LED light, blue and violet wavelengths 9.7 mm light head diameter	LED light, blue and violet wavelengths 9.7 mm light head diameter	Same
Accessories	LOOP Protective Barrier Sleeves, LOOP Protective Light Shield	Barrier Sleeve VALO®, VALO® Cordless Light Shield	Same
Composition of Materials	Plastic Housing design ABS, various colors	Aluminum, anodized various colors	Substantially equivalent
Sterility	Supplied Non-sterile	Supplied Non-sterile	Same
Parameters of Disinfection	Chemical disinfection with approved cleaning/sanitizing agents: Cavicide products (non-bleach) Isopropyl alcohol Lysol disinfectant (alcohol-based only) FD 366 (Dürr Dental)	Chemical disinfection with approved cleaning/sanitizing agents: Cavicide products (non-bleach) Isopropyl alcohol Ethyl alcohol based cleaners Lysol disinfectant (alcohol-based only)	Same
Usability/Ergonomics	3 buttons – 1 cure power, 1 mode select, 1 time select	2 buttons – 1 cure power, 1 mode select	Substantially equivalent

VII. Performance Data

The following performance data 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 and 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

- Test Performed
- S-LED Design Verification and Plan Report
- Vibration, Shock and Environmental Test
- 3-year wand lifecycle durability verification
- 3-year durability test report
- Clinicians Report – results of in-house evaluation of LOOP prototype
- Long Term Battery Test
- Characterization of Curing Light Tips
- Beam Analysis
- LOOP IFU Spectrum Generation
- ISO 10650-2: 2018 – Powered Polymerization Activators
- Drop and Ingress Testing
- Tip Rotation Life Test
- Top Arm Lift Test and Calibration Reliability Test
- Pin Connection Reliability Test
- Test IFU Recommended Cleaning Solutions on CLCL and Accessories
- Evaluation of Lens Hardness

- Testing Production Barrier Sleeve Effects on CLCL Wand
- Functional Thermal Humidity
- Reflectance Variation Testing
- Material Compare for RevJ BSleeve
- Testing Irradiance Penetration from composites
- Light Shield Effects on Reflectance Measurements
- MARC-LC Certification
- GDS-CLCL-2 Irrad Calibration
- CLCL-5 MARC Correlation
- Centroid Device Tolerance Template
- Optical Inspection
- Re-Testing the CLCL Shield for light blocking effectiveness
- UL746CReview
- Testing CLCL reflectance detection of angled surfaces
- Turn on/off Distances of LOOP during In Vivo use
- Testing Auto Start Distances on Human Tissue
- Testing CLCL function over various dental materials
- CLCL Benchmark Irradiance Output at various distances
- Service Battery
- CLCL Mechanical Attribute Examination
- Touch Temp Verification
- Elect Leakage and Dielectric

Animal and Clinical Studies

No animal or clinical studies were conducted.

VIII. Conclusion

The LOOP™ LED Curing Light System (rev K) is substantially equivalent to the predicate device, the LOOP™ LED Curing Light System (rev H). Both devices have the same intended use/users, have the same level of power output, are hand-held dental curing lights and both produce blue and UV wavelengths. The differences are in the material that the housing is made from and the user-selectable ability to disable the “closed loop” feature.