November 24, 2020

CAO Group, Inc.
Robert Larsen
Regulatory Affairs Manager
4628 West Skyhawk Drive
West Jordan, Utah 84084

Re: K201904
Trade/Device Name: Monet Curing Laser
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet activator for polymerization
Regulatory Class: Class II
Product Code: QNF, GEX
Dated: August 19, 2020
Received: August 26, 2020

Dear Robert Larsen:

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)*
K201904

Device Name
Monet Curing Laser

Indications for Use *(Describe)*
The Monet Curing Laser 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Number: K201904

Applicant Information:

Company Name: CAO Group, Inc.
Company Address: 4628 West Skyhawk Drive
West Jordan, Utah 84084 U.S.A.
Company Phone: 1-801-256-9282
Company Fax: 1-801-256-9287

Contact Person: Robert K. Larsen

Preparation Date: November 20, 2020

Device Name:

Trade Name: Monet Curing Laser
Common Name: Ultraviolet Activator for Polymerization
Product Code: EBZ, GEX
Regulation: 872.6070, 878.4810
Product Classification: Class II

Legally Marketed Predicate Devices for Substantial Equivalence:

PRIMARY PREDICATE DEVICE-
Valo Grand, manufactured by Ultradent Products, Inc. (K160551)

Description of Submitted Device:

The Monet Curing Laser is a device for delivering light energy to dental restorative materials and adhesives, which utilize the light energy to affect a photopolymerization reaction. This energy is generated by a solid-state laser diode, which provides a consistent and reliable generation of laser energy at 450 ± 5nm for a maximum of 2.0 watts (2400 mW/cm^2) of energy output. The laser energy is delivered to the dental material by means of an optical focusing lens that collimates the laser energy to a nearly parallel beam size that remains highly consistent regardless of distance to the target material. The device also includes a low-intensity aiming beam feature that allows the operator to see the delivery site of the energy without risk of premature polymerization of the material.

The device features a metal construction with glass output window that contains all device electronics. The device features a simple on/off switch and set 3-second activation time. The device incorporates a detachable rechargeable battery which is recharged on an accompanying charging stand. The charging stand incorporates a basic radiometer to allow the user to confirm the output intensity of the emitted light.

Indications for Use of the Submitted Device:

The Monet Curing Laser is a source of illumination for curing photo-activated dental restorative materials and adhesives.

Rationale for Substantial Equivalence:

The submitted device features an identical Indications for Use as the predicate device. The submitted device shares similarities in materials of construction, intended operator, basic design principle of emitting high intensity blue light to initiate a polymerization reaction of the target dental material or adhesive. The submitted device operates from an internal rechargeable battery, the same as the predicate device. The submitted device includes a charging stand to recharge the batteries, the same as the predicate device. The submitted device is capable of photopolymerizing, or curing, the intended dental materials and adhesives, the same as the predicate device.

The submitted device differs from the predicate device in that the submitted device uses a laser diode to generate coherent, narrow spectrum light photons, whereby the predicate device uses a light-emitting-diode to generate non-coherent, broad spectrum light photons. The submitted device differs from the predicate device where the predicate device features more operational controls (number of user interface buttons and indicators) and choices of different emission times and intensities, where the submitted device provides only one interface button and one indicator, and provides for only one emission time and one emission intensity. The submitted device incorporates a low-intensity aiming beam to aid the clinician in positioning the device prior to high-intensity emissions, a feature that is absent from the predicate device. The submitted device includes laser protective eyewear, where the submitted device provides a filter shield that affixes to the device.

Performance Data:

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY

The Monet Curing Laser is designed to comply with the performance requirements of 21 CFR 1040.10 and 1040.11, with permissible deviations relative to Laser Notice 50, dated June 24, 2007. The device also complies with the recognized standards of IEC 60601-2-22 Edition 3 and IEC 60825-1 Edition 2. The device is designed in compliance to the entirety of IEC 60601-1: Edition 3.1, IEC 60601-1-2 Edition 4, and IEC 60601-1-6 Edition 3.1.

PERFORMANCE BENCH TESTING

Depth of cure testing was performed with the Monet and with the VALO curing light, assessing different popular brands of dental composite and lighter and darker shades of composite from each of these brands. Both light sources were activated for a single exposure of the same amount of time. The Monet is capable of achieving polymerization of the tested composites at a level that is generally equal to or better than the VALO while doing so with a lower light intensity.

BIOCOMPATIBILITY

The submitted device features the same nature of incidental patient contact as the predicate device. The submitted device is composed of similar materials to that of the predicate device. The submitted

device is intended as a reusable article, the same as the predicate device, except for the single-use barrier sleeve, which is also similar to that of the predicate device.

END-USER STERILIZATION
No portions or aspects of the submitted device are intended to be sterilized by the end-user prior to use, nor are any portions provided to the end-user in a sterile state. The submitted device includes single-use barrier sleeves to aid in infection control. The barrier sleeve is not provided in a sterile state, and is not intended to be sterilized by the end-user prior to use.

Conclusion:

The Monet Curing Laser is substantially equivalent to the listed predicate device without raising any new issues of safety or effectiveness. This device shares an identical intended use, similar principles of basic use and function, and similar performance characteristics. The device is designed to comply with relevant federal and international safety and performance standards.