



Food and Drug Administration
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November 13, 2015

National Dental Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K152936

Trade/Device Name: Sirius Max Diode Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: October 29, 2015
Received: November 3, 2015

Dear Mr. Job:

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 yours,

A handwritten signature in black ink that reads "Susan Runna DDS, MA". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152936

Device Name

SiriusMax Diode Curing Light

Indications for Use (Describe)

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.

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

NDI's Sirius Max Diode Curing Light

Submitted for: National Dental Inc.,
3-149 Collier St.
Barrie, Ont. Canada
Phone: 800-392-1171
Facsimile: 800-262-6888
Contact Person: Cliff Magneson
Date Prepared: 25 October 2015

Device Proprietary Name(s): Sirius Max Diode Curing Light
Common or Usual Name: 400 nm Diode Curing Light (Class II Curing Light)
Product Classification: Ultraviolet activator for polymerization
Product Code: EBZ
Predicate Device(s): VALO CORDLESS K110582

Rationale for Substantial Equivalence

Both the subject and predicate Curing Light device share similar intended uses technical characteristics, features, and specifications. The Curing Light characteristics of the Sirius Max Diode Curing Light, including working wavelengths and outputs, Curing Light delivery methods, safety features, and performance specifications are similar to those of the cleared *Ultradent Valo Cordless* Diode Curing Light. The Curing Light operating system and controls of the subject device are similar to those used by the previously-cleared predicate device showing substantial equivalence. Safety and performance test results have been shown to satisfy applicable international standards recognized by the Agency.

Intended Uses and Indications for Use

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.

Device Description

The Sirius Max Diode Curing Light is shipped as a system consisting of the charging station (“charger”), the handpiece, 50 SiriusMax Barrier Sleeves, an orange protective eye shield, and screwdriver for removal of the battery. The charger allows for placement of the handpiece in a holder with electrical connection for battery charging and interface with the 5vdc power source. The handpiece is constructed of aluminum with plastic control surface and glass output lens and is non-sterile utilizing the barrier sleeves for infection control. The handpiece houses the control circuitry with microprocessor and user interface for selection of mode and curing light output providing visual indications of power settings and of the unit’s status. This interface also features the unit’s power ON/OFF switch as well as the button to activate the white light intraoral illumination light to aid in the visualization of dental anatomy. The unit is battery operated and contains an internal battery pack with Li batteries. The battery pack is service removable with the use of the screwdriver provide. An instruction for use is also included inside the packaging. The Instructions For Use detail the function of the device and describe the 6 different curing modes. They are Normal mode 1200mw/cm², Softstart mode 1400mw/cm², Pulse mode 1400mw/cm², High Power mode 1300 mw/cm², Xtra Power mode, 3000mw/cm², and Orthodontics mode 1400mw/cm². The curing LED module provides high intensity light in the range of 430-490nm. The white light transillumination LED module (400-700nm) is provided as an aid for illuminating anatomy in the oral cavity.

Conformity to International Standards

The Sirius Max Diode Curing Light complies with the performance requirements as the predicate device: IEC 60601-1, IEC 60601-2-2, , and IEC 60601-2-22, ANSI/ADA 48-2. The following tests were performed in addition to bench tests described in the 510(k); depth of cure, conformance to ANSI/ADA Specification No. 48-2, Temperature Control Validation, cleaning and disinfection validation, software verification and validation and IEC 60601-1 Electrical Safety.

Comparative Performance Data

The Sirius Max Diode Curing Light has been tested side-by-side against the predicate device. Measurements of the output of the subject devices output ranging from 0.1 to 5.0W output all modes were shown to vary from the unit’s settings by an average of only 1.4% in all modes. The intended performance of these devices, based on IEC 60601- 2-22, is that Curing Light output should vary from the device’s setting by less than $\pm 20\%$ of the setting. Both the subject and predicate devices have been shown to satisfy this standard.

Comparison of Features and Characteristics

Table 1, following, lists key Features and Characteristics of the subject and predicate devices. Note that the slight change in verbiage of Indications for Use is intended to more accurately describe the process of photo-activation of dual cured materials where curing is initiated but not completed by the light activation process. The SiriusMax also has 9 different timer settings for the curing modes compared to 8 found on the predicate device however, output intensities are in the same range and testing was done to validate the depth of cure and confirm substantial equivalence. The SiriusMax has a single Peak wavelength at 460nm whereas the predicate device has a primary peak at 460nm and a small peak at 410nm. The low energy of the small peak at 410nm combined with the fact that the violet wavelengths have lower penetration depth than blue wavelengths makes the 460nm the predominant activator and therefore the subject and predicate are substantially equivalent.

	NDI Sirius Max Diode Curing Light		Ultradent Products Inc. Valo Cordless
Indications for use	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.		Source of illumination for curing photo-activated dental restorative materials and adhesives.
Product Code	EBZ		EBZ
Regulation Number	21 CFR 872.6070		21 CFR 872.6070
Device Class	II		II
Classification Panel	Dental		Dental
Common Name of Classification	Ultraviolet activator for polymerization		Ultraviolet activator for polymerization
Light Source	Solid State Light Emitting Diode		Solid State Light Emitting Diode
Power Requirements	10w5vDC supplied from 110-240VAC 50-60Hz		100-240VAC@50-60Hz
Peak Wavelength	460nm		460nm small peak at 410nm
Maximum Power	3000 mW/cm ²		3,200 mW/cm ²
Light Intensity and Pulse Characteristics	Normal 1200mw/cm ² 10,20 sec SoftStart 1400mw/cm ² 15 sec Pulse 1400mw/cm ² 5,10 sec HighPower1400mw/cm ² 5 sec XtraPower 3000mw/cm ² 1, 3 sec Orthodontics 1400mw/cm ² , 10 x 3 sec		Standard Power (1000mw/cm ²) 5,10,15,20 seconds High Power (1400mw/cm ²) 1,2,3,4 seconds XtraPower Mode (3200mw/cm ²) 3 seconds only
Cooling System	Convection Cooled		Convection Cooled
Pulse Control	Digital Emission Control		Digital Emission Control
Curing Light Source	Solid-state Light Emitting Diode		Solid-state Light Emitting Diode
Materials	Aluminum body, glass lens, plastic controls		Aluminum body, glass lens, plastic controls
User Interface	Membrane Touch Pad, OLED Display		Membrane Touch Pad, LED Display
Sterile Barrier	FDA Cleared Disposable Sleeve/sheath		FDA Cleared Disposable Sleeve/sheath
510k Number	Pending		K110582

Conclusion

The subject device shares the same principle of operation as the predicate device. Both are LED solid state diode Curing Lights that emit radiant energy at an approximate peak wavelength of 460 nm (nom) with outputs that range from 0.1 to 5.0W. Both deliver Curing Light energy to subject target material(s) controlled by trained, experienced clinicians. They share the same indications for use. Both have been found to satisfy international safety standards relating to electrical medical devices in general and dental Curing Lights in particular. They share similar safety labeling, and associated safety features. Both the subject and predicate device's outputs were measured and compared to their settings to determine the accuracy of the devices controls. Both met international standards pertaining to accuracy of output of photonic emissions.

The Sirius Max Diode Curing Light device shares intended uses, principle of operation, technical attributes, functional capabilities, biocompatibility standards and performance characteristics with the listed predicate device. Both the subject and predicate device have been shown to comply with applicable Federal and international safety and performance standards. Our conclusion is that the Sirius Max Curing Light is substantially equivalent to the listed predicate device.