DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Kerr Corporation
% Mohammad Ansari
Regulatory Affairs Specialist II
Sybron Dental Specialties
1717 W. Collins Ave
Orange, California 92867

July 18, 2017

Re: K163064
Trade/Device Name: Demi Ultra
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: June 27, 2017
Received: June 28, 2017

Dear Mohammad Ansari:

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

for
Lori Wiggins
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)*
(Not yet assigned) K163064

Device Name

Demi Ultra

Indications for Use *(Describe)*
The Demi Ultra is a Light Emitting Diode (LED) visible light curing device used for the polymerization of light-cured materials by dental professionals.

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 DEMI ULTRA

Demi Ultra
K163064

1. Submitter Information**:**

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92687

Contact Person: Mohammad Saad Ansari
Telephone Number: 714-516-7334
Fax Number: 909-962-5694
Date Prepared: July 13, 2017

2. Device Name:

Classification Name	Ultraviolet activator for polymerization
Proprietary Name	Demi Ultra
FDA CDRH Panel	Dental
Product Code	EBZ
Regulation Number	872.6070
Class #	II

3. Predicate Device:

The proposed Demi Ultra is substantially equivalent to the legally marketed device Demi Ultra (K123468) cleared on March 20, 2013, product code EBZ.

4. Description of Device:

The Demi Ultra is a Light Emitting Diode (LED) visible light curing device used for the polymerization of light-cured materials by dental professionals. The Demi Ultra consists of a handpiece, LED light curing attachment, and charging dock. The aluminum and plastic molded handpiece contains two (2) ultracapacitors (electric double-layer capacitors), printed circuit boards containing the electronics and user interface buttons, receptacle for retaining the LED light curing attachment, and receptacle for interfacing with the charging dock. The LED light curing attachment contains the curing LED, clear lens and two (2) copper head spreaders, all over molded in plastic. The charging dock contains printed circuit boards containing electronics to support charging the handpiece and built-in LED radiometer functionality. For the handpiece, a digital circuit and microprocessor is utilized to control three (3) different curing modes (5, 10 and 20 seconds). Each mode specifies LED curing output and optional audible beep timing. The

handpiece uses one button to activate the LED curing output and another to select the curing time mode. For the charging dock, a digital circuit and microprocessor is utilized to monitor the charging of the handpiece ultracapacitors, as well as respond to light at the radiometer input by illuminating lights on a radiometer meter. Demi Ultra is required to be used with an FDA cleared barrier sleeve.

5. Statement of Intended Use:
The Demi Ultra is a Light Emitting Diode (LED) visible light curing device used for the polymerization of light-cured materials by dental professionals.

6. Indications For Use
The Demi Ultra is a Light Emitting Diode (LED) visible light curing device used for the polymerization of light-cured materials by dental professionals.

7. Summary of Non-Clinical Performance Data:
The technological characteristics of Demi Ultra are identical to the predicate Demi Ultra (K123468). The following performance tests were completed during the product lifecycle:

Depth of Cure
Irradiance with Light Intensity and Peak Wavelength per ISO 10650:2015 and ANSI/ADA 48-2:2010
Charge Time and Run Time
Biocompatibility per ISO 10993
Electromagnetic Compatibility (EMC) and Electrical Safety Testing per IEC 60601
Software Validation

A cleaning validation study on manual cleaning efficacy was performed on the worst case use conditions following the FDA Guidance: *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*

8. Summary of Technological Characteristics:

Element	Predicate Demi Ultra	Proposed Demi Ultra
510(k) number	K123468	K163064
Trade Name	Demi Ultra	Demi Ultra
Product Classification	Class 2	Class 2
Product Code	EBZ	EBZ
Cordless	Yes	Yes
Light Source	LED	LED
Handpiece power source	2 Ultracapacitors	2 Ultracapacitors
AC supply connection	100-240V AC, 1.0-0.5A, 50-60 Hz	100-240V AC, 1.0-0.5A, 50-60 Hz
Operating time	4 minutes	4 minutes, 10 seconds
Recharge Time	35 seconds, 60 seconds	40 seconds, 70 seconds
Built-in radiometer	Yes	Yes
Microprocessor control	Yes (8-bit uc)	Yes (8-bit uc)

Element	Predicate Demi Ultra	Proposed Demi Ultra
Power status indicator	Yes	Yes
Standard light guide	8mm tapered	8mm tapered
Reusable light guide	Yes	Yes
User replaceable power source	No	No
Handpiece digital display	No (LED indicators)	No (LED indicators)
User selectable (operational) curing modes	(5, 10 & 20 seconds)	(5, 10 & 20 seconds)
Cooling fan	No	No
Audible beep	Yes	Yes
Continuous curing	Yes	Yes
Handpiece Material	Valox 357U	Valox 357U
Charging Base Material	Valox 357U	Valox 357U
LED Light Attachment (LLA)	HX215HP	HX420HP
Light Shield	Lexan 243R or Lexan 143	Sumitomo SD2173M
Peak wavelength	450-470 nm	450-470 nm
Wavelength range @ 50% (spectrum)	438-485 nm	438-485 nm
Typical output intensity: 400-500 nm, using 8mm turbo light guide	1100mW/cm^2 pulsed to 1330mW/cm^2	1100mW/cm^2 pulsed to 1330mW/cm^2

9. Clinical Performance Data

Design Validation activities were performed as required per 21CFR820.30

10. Conclusion as to Substantial Equivalence

The modifications made to Demi Ultra do not affect the intended use of the device, indications for use, or alter the fundamental scientific technology of the device. The technological characteristics of the subject device Demi Ultra are very similar to the predicate Demi Ultra (K123468). The proposed Demi Ultra has similarities in select performance characteristics and all design features as compared to the predicate. The nonclinical performance testing demonstrates that the Demi Ultra performs as well as the predicate device Demi Ultra. Demi Ultra is indicated to be used with a FDA cleared barrier sleeve. Based on biocompatibility studies, identical intended use and indications for use, and performance characteristics, the Demi Ultra is substantially equivalent to the predicate Demi Ultra (K123468).