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

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
510(k) Number (if known)  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.

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

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTAFF@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
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:

<table>
<thead>
<tr>
<th>Element</th>
<th>Predicate Demi Ultra</th>
<th>Proposed Demi Ultra</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) number</td>
<td>K123468</td>
<td>K163064</td>
</tr>
<tr>
<td>Trade Name</td>
<td>Demi Ultra</td>
<td>Demi Ultra</td>
</tr>
<tr>
<td>Product Classification</td>
<td>Class 2</td>
<td>Class 2</td>
</tr>
<tr>
<td>Product Code</td>
<td>EBZ</td>
<td>EBZ</td>
</tr>
<tr>
<td>Cordless</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Light Source</td>
<td>LED</td>
<td>LED</td>
</tr>
<tr>
<td>Handpiece power source</td>
<td>2 Ultracapacitors</td>
<td>2 Ultracapacitors</td>
</tr>
<tr>
<td>AC supply connection</td>
<td>100-240V AC, 1.0-0.5A, 50-60 Hz</td>
<td>100-240V AC, 1.0-0.5A, 50-60 Hz</td>
</tr>
<tr>
<td>Operating time</td>
<td>4 minutes</td>
<td>4 minutes, 10 seconds</td>
</tr>
<tr>
<td>Recharge Time</td>
<td>35 seconds, 60 seconds</td>
<td>40 seconds, 70 seconds</td>
</tr>
<tr>
<td>Built-in radiometer</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Microprocessor control</td>
<td>Yes (8-bit uc)</td>
<td>Yes (8-bit uc)</td>
</tr>
<tr>
<td>Element</td>
<td>Predicate Demi Ultra</td>
<td>Proposed Demi Ultra</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Power status indicator</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Standard light guide</td>
<td>8mm tapered</td>
<td>8mm tapered</td>
</tr>
<tr>
<td>Reusable light guide</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>User replaceable power source</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Handpiece digital display</td>
<td>No (LED indicators)</td>
<td>No (LED indicators)</td>
</tr>
<tr>
<td>User selectable (operational) curing modes</td>
<td>(5, 10 &amp; 20 seconds)</td>
<td>(5, 10 &amp; 20 seconds)</td>
</tr>
<tr>
<td>Cooling fan</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Audible beep</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Continuous curing</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Handpiece Material</td>
<td>Valox 357U</td>
<td>Valox 357U</td>
</tr>
<tr>
<td>Charging Base Material</td>
<td>Valox 357U</td>
<td>Valox 357U</td>
</tr>
<tr>
<td>LED Light Attachment (LLA)</td>
<td>HX215HP</td>
<td>HX420HP</td>
</tr>
<tr>
<td>Light Shield</td>
<td>Lexan 243R or Lexan 143</td>
<td>Sumitomo SD2173M</td>
</tr>
<tr>
<td>Peak wavelength</td>
<td>450-470 nm</td>
<td>450-470 nm</td>
</tr>
<tr>
<td>Wavelength range @ 50% (spectrum)</td>
<td>438-485 nm</td>
<td>438-485 nm</td>
</tr>
<tr>
<td>Typical output intensity: 400-500 nm, using 8mm turbo light guide</td>
<td>1100mW/cm² pulsed to 1330mW/cm²</td>
<td>1100mW/cm² pulsed to 1330mW/cm²</td>
</tr>
</tbody>
</table>

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).