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

December 21, 2016

Re: K162436

Trade/Device Name: EndoVac Pure
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: NYL
Dated: November 22, 2016
Received: November 25, 2016

Dear Mr. 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](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](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](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm).

Sincerely,

[Signature]

Tina Kiang, Ph.D.
Acting 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

Device Name
EndoVac Pure™

Indications for Use (Describe)
The EndoVac™ Pure System is intended for the delivery and evacuation of endodontic irrigation solutions and removing debris of injured or necrotic pulp tissue during root canal procedures.

Type of Use (Select one or both, as applicable)

- [x] 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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K162436
510(k) SUMMARY

1. **Submitter Information:**
   Sybron Dental Specialties
   1717 W. Collins Ave.
   Orange CA, 92867

   Contact Person: Mohammad Saad Ansari
   Telephone Number: 909-962-5644
   Fax Number: 909-962-5694

   Date Prepared: December 22, 2016

2. **Device Name:**
   - Proprietary Name: EndoVac Pure
   - Classification Name: Handheld controller, air-powered, root canal irrigation
   - CFR Number: 872.4200
   - Device Class: Class I
   - Product Code: NYL

3. **Predicate Device:**
The EndoVac Pure™ product is substantially equivalent to the legally marketed device EndoVac® Apical Negative Pressure Irrigation System (K140685) cleared on July 2nd, 2014, product code NYL.

4. **Description of Device:**
The EndoVac Pure™ system builds on the EndoVac System and presents a unique way to irrigate during root canal treatments. The system is an apical negative pressure system that draws fluid apically by way of evacuation, reducing the risk of apical irrigant extrusion during root canal procedures. The vacuum is routed through the system and controlled independently through the dental chair vacuum system. The fluid delivery is controlled by peristaltic pumps. The pumps are driven by Printed Circuit Board Assemblies (PCBA) and controlled by Field Programmable Gate Array (FPGA) configuration files.

5. **Intended Use**
The EndoVac Pure™ System is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.

6. **Indications for Use:**
The EndoVac Pure™ System is intended for the delivery and evacuation of endodontic irrigation solutions and removing debris of injured or necrotic pulp tissue during root canal procedures.

7. Description of Safety and Substantial Equivalence:

The EndoVac Pure™ product is substantially equivalent to the legally marketed device EndoVac® Apical Negative Pressure Irrigation System (K140685) cleared on July 2nd, 2014, product code NYL.

Technological Characteristics
Non-Clinical Performance Data

The technological characteristics of EndoVac Pure™ is very similar to the predicate EndoVac® (K140685) negative pressure irrigation systems. The EndoVac Pure™ and the predicate EndoVac System (K140685) perform the same function, which is a method to deliver irrigant, rinse and evacuate during root canal procedures. The following performance tests were conducted as part of design verification:

- Flow Rate Delivery and Selection
- Suction Flow Rate Performance
- Cleaning and Disinfection Validation
- Biocompatibility
- Sterilization Validation
- Shelf Life Validation
- Electromagnetic Compatibility (EMC) Testing
- Electrostatic Discharge (ESD) Suppression
- MicroCannula Suction Performance

Applicable Standards

- ISO 14971: 2007 Medical Devices – Application of risk management
- ISO 10993-7:2008: Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10:2009 Biological Evaluation of Medical Devices Part 10 - Tests for irritation and skin sensitization
- IEC 60601-1 Issued: 2005/01/01 Ed: 3 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 62304:2006/Amd 1:2015 Medical device software – Software life cycle processes
- ISO 11607-1:2006 Packaging for Terminally Sterilized Medical Devices
- ISO 11607-2:2006 Packaging for Terminally Sterilized Medical Devices Part 2: Validation requirements for forming, sealing and assembly processes

Table 7.1: Predicate and Proposed Device Comparison Table

<table>
<thead>
<tr>
<th>Element</th>
<th>Predicate EndoVac System</th>
<th>Proposed EndoVac Pure</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k)</td>
<td>K140685</td>
<td>K162436</td>
</tr>
<tr>
<td>Trade Name</td>
<td>EndoVac Apical Negative Pressure Irrigation System</td>
<td>EndoVac Pure™</td>
</tr>
<tr>
<td>Class</td>
<td>Class 1</td>
<td>Class 1</td>
</tr>
<tr>
<td>Product Code</td>
<td>NYL</td>
<td>NYL</td>
</tr>
<tr>
<td>Classification Name</td>
<td>Handheld controller, Air-Powered, Root Canal Irrigation</td>
<td>Handheld controller, Air-Powered, Root Canal Irrigation</td>
</tr>
<tr>
<td>Target Users</td>
<td>Licensed Dental Professionals</td>
<td>Licensed Dental Professionals</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The EndoVac system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.</td>
<td>The EndoVac Pure™ system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.</td>
</tr>
<tr>
<td>Indications For Use</td>
<td>The EndoVac system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.</td>
<td>The EndoVac Pure™ System is intended for the delivery and evacuation of endodontic irrigation solutions and removing debris of injured or necrotic pulp tissue during root canal procedures.</td>
</tr>
<tr>
<td>Device Components</td>
<td>Syringes, Multi-Port Adapter, Master Delivery Tip, Fingerpiece, Handheld</td>
<td>Base Unit, HVE Adapter, Handheld controller, Apex Cartridge (with MicroCannula and MacroCannula),</td>
</tr>
<tr>
<td>Element</td>
<td>Predicate EndoVac System</td>
<td>Proposed EndoVac Pure</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td></td>
<td>controller, MicroCannula and MacroCannula, Connection tubing,</td>
<td>AC Supply, Universal Latches, Connection tubing,</td>
</tr>
<tr>
<td>Suction Adapter</td>
<td>The Multi-Port Adapter critical to functionality dimension in this component is the Outer Diameter (OD) due to compatibility with dental chair high evacuation line OD = 0.434 in)</td>
<td>HVE adapter: Critical to functionality dimension in this component is the Outer Diameter (OD) due to compatibility with dental chair High evacuation line (OD = 11.0 ±0.1 mm) (0.434 in)</td>
</tr>
<tr>
<td>Fluid Delivery Feature</td>
<td>Delivery Needle in Master Delivery Tip and Luer Lock Connection</td>
<td>Delivery Needle in Apex Cartridge and Handheld controller Connection</td>
</tr>
<tr>
<td>MacroCannula Dimensions</td>
<td>The MacroCannula critical to functionality dimension in this component is the OD due to the clinical application into the root canal cleaning procedure (OD = 0.020 ±0.001 in)</td>
<td>MacroCannula on Apex Cartridge critical to functionality dimension in this component is the OD due to the clinical application into the root canal cleaning procedure (OD = 0.595 ±0.012 mm) (0.023 inch)</td>
</tr>
<tr>
<td>MacroCannula material</td>
<td>Titan Petchem SM598 (Ethylene Propylene Copolymer) / colorant (BLMT 2070)</td>
<td>Polyamide (PI)</td>
</tr>
<tr>
<td>MicroCannula Dimensions</td>
<td>MicroCannula critical to functionality dimension in this component is the OD due to the clinical application into the root canal cleaning procedure (OD = 0.0125 to 0.0118 in)</td>
<td>MicroCannula on Apex Cartridge critical to functionality dimension in this component is the OD due to the clinical application into the root canal cleaning procedure (OD = 0.0125 to 0.0118 in)</td>
</tr>
<tr>
<td>MicroCannula Material</td>
<td>AISI 304 Stainless Steel</td>
<td>AISI 304 Stainless Steel</td>
</tr>
<tr>
<td>Mounting System</td>
<td>None</td>
<td>Universal Latch</td>
</tr>
<tr>
<td>Mode of Operation</td>
<td>Manually Operated</td>
<td>Manually Operated</td>
</tr>
<tr>
<td>Fluid Delivery System</td>
<td>Manual operation of syringe plunger</td>
<td>Base Unit contains two peristaltic pumps that are manually operated by fluid delivery buttons in the handheld controller</td>
</tr>
<tr>
<td>AC Supply Connection</td>
<td>None</td>
<td>100-240V AC, 1.0-0.5A, 50-60Hz</td>
</tr>
<tr>
<td>Element</td>
<td>Predicate EndoVac System</td>
<td>Proposed EndoVac Pure</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Flow Uptake</td>
<td>MicroCannula uptake flow 5ml/min ± 15%</td>
<td>MicroCannula uptake flow 5ml/min ± 15%</td>
</tr>
<tr>
<td></td>
<td>MacroCannula uptake flow 40ml/min ± 20%</td>
<td>MacroCannula uptake flow 40ml/min ± 20%</td>
</tr>
<tr>
<td>MicroCannula, Working Length</td>
<td>MicroCannula working length is from 14 to 30 mm ±0.5 mm</td>
<td>MicroCannula working length is from 14 to 30 mm ±0.5mm</td>
</tr>
<tr>
<td>System Purge</td>
<td>Remove syringe plunger and empty each syringe, manually push the plunger to empty each syringe</td>
<td>Double press purge button to empty each reservoir</td>
</tr>
</tbody>
</table>
| Hood Design                     | 1 Configurations  
Master Delivery Tip Hood                                                        | 2 Configurations  
MacroCannula Hood  
Apex Irrigation Hood                                                                    |
| Vacuum Evacuation System        | MicroCannula and MacroCannula are two independent single use components                  | Single Use, sterile Apex Cartridge includes coaxial MicroCannula and MacroCannula      |
| Vacuum Connection               | Multi-Port Adapter                                                                         | HVE Adapter                                                                             |
| Liquid Storage                  | Syringes  
20 ml syringe NaOCl  
3 ml syringe EDTA                                                                          | Liquid Reservoirs  
100 ml NaOCl  
25 ml EDTA                                                                            |
<p>| Unclogging Mechanism            | Requires MacroCannula and MicroCannula to be disconnected from the vacuum line. The MacroCannula and MicroCannula are independently connected to another syringe and positive pressure is applied to dislodge and unclog any debris. | Built-in unclogging mechanism allows MacroCannula and MicroCannula without disconnecting from the vacuum line. The MicroCannula can be used to drive out any clogged debris in the MacroCannula by sliding in and out of it. The MicroCannula can be pulled back into the MacroCannula removing any debris on the external sides of the MicroCannula. The MicroCannula can also be pulled back into the head of the Apex Cartridge system allowing maximum vacuum pressure to dislodge any clogged debris on the inside of the MicroCannula. |
| MicroCannula and MacroCannula   | Negative pressure used to clean root canal on both MicroCannula and MacroCannula. MacroCannula doesn't require | Negative pressure used to clean root canal on both MicroCannula and MacroCannula. MacroCannula doesn't require any |</p>
<table>
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<tbody>
<tr>
<td>Cross contamination (cleaning, disinfection, sterilization)</td>
<td>any working length measurement but can be adjusted by clinician if needed. MicroCannula working length utilizes a sliding rubber stop as a datum and can be used to set the working length. The rubber stop may move accidentally if pressure is applied to it.</td>
<td>working length measurement but can be adjusted by clinician if needed. MicroCannula working length utilizes a rigid hood as a datum and a ratcheting slider to set the working length. The ratchet on the slider prevents the working length from being adjusted inadvertently.</td>
</tr>
</tbody>
</table>
| Alarm System                              | None                                                                                      | Alarm at Device Malfunction. Multiple alarms have been incorporated in the EndoVac Pure™ system to alert the user in case of issues that may affect the clinical outcome.  
- Issue #1 - Low fluid with an audible alarm and yellow flashing light  
- Issue #2 - System malfunction with a red flashing light |                                                                                  |
| Adverse Tissue Reaction and Biocompatibility | Meets requirements                                                                         | Meets requirements                                                                     |
| Electromagnetic Compatibility             | None                                                                                      | Meets requirements                                                                     |
| Sterilization Validation                  | Meets requirements                                                                         | Meets requirements                                                                     |
| Software Validation                       | Not Applicable                                                                             | Meets requirements                                                                     |

8. **Clinical Performance Data**  
Clinical performance testing has not been performed for EndoVac Pure™.

Premarket Notification          EndoVac Pure          Sybron Dental Specialties          Page 6 of 7
9. **Conclusion as to Substantial Equivalence**

The EndoVac System (K140685) and the proposed EndoVac Pure™ have the same Intended Use: for the delivery and evacuation of endodontic irrigation solutions during root canal procedures. The proposed Indications for Use statement adds "and removing debris of injured or necrotic pulp tissue” to better describe root canal cleaning and the setting and use-site environment where the system is used. The EndoVac Pure™ is a less-complex non-automated technology. The technological characteristics of EndoVac Pure™ are very similar to the predicate EndoVac System (K140685). The proposed EndoVac Pure™ has similarities in select performance characteristics and design features as compared to the predicate. The technological characteristics of EndoVac Pure™ are very similar to the predicate EndoVac (K140685) negative pressure irrigation systems. The EndoVac Pure™ and the predicate EndoVac System (K140685) perform the same function, which is a method to deliver irrigant, rinse and evacuate during root canal procedures. The proposed EndoVac Pure™ is substantially equivalent to the predicate EndoVac System (K140685) based on design, performance, biocompatibility testing, and the intended use. Any noted differences in technological characteristics between the proposed and predicate products do not raise new questions of safety and effectiveness. The EndoVac Pure™ and the predicate EndoVac System (K140685) perform the same function, which is a method to deliver irrigant, rinse and evacuate during root canal procedures. Based on biocompatibility studies, identical intended use, and performance characteristics, the EndoVac Pure™ is substantially equivalent to the predicate EndoVac System (K140685).