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

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. 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,

Susan Runner DDS, MA

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

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)*

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)*

☒ 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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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 10993-1**:**2009 Biological Evaluation of Medical Devices Part 1 - Evaluation and Testing
- ISO 10993-5**:**2009 Biological Evaluation of Medical Devices Part 5 - Tests for in vitro cytotoxicity
- ISO 10093-7:2008: 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 60601-1-2**:**2007 Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (3rd Edition)
- IEC 60601-1-2**:**2014 Medical electrical equipment Part 1-2: General requirements for

safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (4th Edition)

- IEC 62304:2006/Amd 1:2015 Medical device software – Software life cycle processes
- ISO 11135:2014 Sterilization of healthcare products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 14937: 2009 Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.
- ISO 11138:2006 Sterilization of healthcare products – Biological indicators –Part 1: General requirements, Part 2: Biological indicators for ethylene oxide sterilization processes
- ISO 14161:2009 Sterilization of healthcare products – Biological indicators – Guidance for the selection, use and interpretation of results.
- 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

Element	Predicate EndoVac System	Proposed EndoVac Pure
510(k)	K140685	K162436
Trade Name	EndoVac Apical Negative Pressure Irrigation System	EndoVac Pure™
Class	Class 1	Class 1
Product Code	NYL	NYL
Classification Name	Handheld controller, Air-Powered, Root Canal Irrigation	Handheld controller, Air-Powered, Root Canal Irrigation
Target Users	Licensed Dental Professionals	Licensed Dental Professionals
Intended Use	The EndoVac system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.	The EndoVac Pure™ system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.
Indications For Use	The EndoVac system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.	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.
Device Components	Syringes, Multi-Port Adapter, Master Delivery Tip, Fingerpiece, Handheld	Base Unit, HVE Adapter, Handheld controller, Apex Cartridge (with MicroCannula and MacroCannula),

Element	Predicate EndoVac System	Proposed EndoVac Pure
	controller, MicroCannula and MacroCannula, Connection tubing,	AC Supply, Universal Latches, Connection tubing,
Suction Adapter	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)	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)
Fluid Delivery Feature	Delivery Needle in Master Delivery Tip and Luer Lock Connection	Delivery Needle in Apex Cartridge and Handheld controller Connection
MacroCannula Dimensions	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)	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)
MacroCannula material	Titan Petchem SM598 (Ethylene Propylene Copolymer) / colorant (BLMT 2070)	Polyamide (PI)
MicroCannula Dimensions	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)	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)
MicroCannula Material	AISI 304 Stainless Steel	AISI 304 Stainless Steel
Mounting System	None	Universal Latch
Mode of Operation	Manually Operated	Manually Operated
Fluid Delivery System	Manual operation of syringe plunger	Base Unit contains two peristaltic pumps that are manually operated by fluid delivery buttons in the handheld controller
AC Supply Connection	None	100-240V AC, 1.0-0.5A, 50-60Hz

Element	Predicate EndoVac System	Proposed EndoVac Pure
Flow Uptake	MicroCannula uptake flow 5ml/min ± 15% MacroCannula uptake flow 40ml/min ± 20%	MicroCannula uptake flow 5ml/min ± 15% MacroCannula uptake flow 40ml/min ± 20%
MicroCannula, Working Length	MicroCannula working length is from 14 to 30 mm ±0.5 mm	MicroCannula working length is from 14 to 30 mm ±0.5mm
System Purge	Remove syringe plunger and empty each syringe, manually push the plunger to empty each syringe	Double press purge button to empty each reservoir
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
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

Element	Predicate EndoVac System	Proposed EndoVac Pure
	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.	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.
Cross contamination (cleaning, disinfection, sterilization)	Meet Requirements Patient contacting portion is Autoclaveable	Meets Requirements Patient contacting portion is single use and sterile. **Handheld controller is cleaned and disinfected between uses, then covered with an FDA cleared dental barrier sleeve which is non-sterile and intended for single patient use only.**
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™.

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).