DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 2, 2014

SybronEndo
C/O Ms. Courtney Clark, CBA, RAC
Regulatory Affairs Manager, Submissions
Sybron Dental Specialties, Incorporated
1717 W. Collins Avenue
Orange, California 92867

Re: K140685
Trade/Device Name: Endo Vac® Apical Negative Pressure Irrigation System
Regulation Number: 21 CFR 872.4200
Regulation Name: Handpiece, Air-Powered, Root Canal Irrigation
Regulatory Class: I
Product Code: NYL
Dated: May 30, 2014
Received: June 2, 2014

Dear Ms. Clark:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Runner -S

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

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K140685

Device Name: EndoVac® Apical Negative Pressure Irrigation System

Indications for Use:

The EndoVac® system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.

Prescription Use ___X___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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SECTION 5. 510(k) SUMMARY

EndoVac® Apical Negative Pressure Irrigation System

1. Submitter Information**:**

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

Contact Person: Courtney Clark
Telephone Number: 714-516-7426
Fax Number: 714-516-7472
Date Prepared: 17 March 2014

2. Device Name:
   - Proprietary Name: EndoVac® Negative Pressure Irrigation System
   - Classification Name: Handpiece, air-powered, root canal irrigation
   - Regulation Description: Dental handpiece and accessories
   - CFR Number: 872.4200
   - Device Class: Class I reserved
   - Product Code: NYL

3. Predicate Device:
EndoVac® Apical Negative Pressure Irrigation System is substantially equivalent to the legally marketed device RinsEndo, manufactured by Air Techniques, K052271 cleared on May 26, 2006, product code NYL.

4. Description of Device:
The EndoVac® System is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures. EndoVac® Apical Negative Pressure Irrigation System is used in root canal therapy and is comprised of four main components. The Multi-Port Adapter is used to connect the Master Delivery Tip to the dental office Hi-Vac system. The Master Delivery Tip provides a constant flow of irrigant that lowers the risk of overflow due to continuous suction. Additional tips include the MacroCannula which is used to remove coarse debris after instrumentation, and the MicroCannula which features microscopic evacuation holes allowing the irrigant to flow to the apical termination.

5. Statement of Intended Use:

The EndoVac® System is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics

The EndoVac® System is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures. EndoVac® Apical Negative Pressure Irrigation System presents a method to effectively irrigate during root canal treatments. Unlike positive pressure systems which use a cannula or side-port needles to deliver irrigants to the canal, the EndoVac® is a negative pressure system that draws fluid apically by way of vacuum suction. Because the system utilizes negative pressure irrigation, irrigants are suctioned from the pulp chamber, apically, to the apical termination and then away into the office Hi-Vac system. The EndoVac® Apical Negative Pressure Irrigation System is comprised of a Multi-Port Adapter which attaches to the dental Hi-Vac system, the Master Delivery Tip which allows for simultaneous irrigation and evacuation, the MacroCannula which removes coarse debris left in the canal from instrumentation, and the MicroCannula which removes microscopic debris at the apical 1 mm via 12 microscopic, laser-drilled holes, each 100 μm in diameter. Other accessories include handpiece and finger-piece attachments, evacuation tubing and syringes.

EndoVac® Apical Negative Pressure Irrigation System is substantially equivalent to the legally marketed RinsEndo dental handpiece manufactured by Airtechniques, Inc. (K052271). The RinsEndo uses a turbine driven dental handpiece to provide hydrodynamic rinsing and flushing of root canals, but has the same intended use as the proposed EndoVac® Apical Negative Pressure Irrigation System. A comparison of the proposed and predicate devices is provided in Table 1.

Table 1: Comparison of Proposed and Predicate Devices

Device Name	Proposed EndoVac® System	Predicate RinsEndo (K052271)
FDA Product Code	NYL; Handpiece, air-powered, root canal irrigation	NYL; Handpiece, air-powered, root canal irrigation
Classification	Class I reserved	Class I reserved
Manufacturer	SybronEndo 1332 South Lone Hill Avenue Glendora CA, 91740	Air Techniques, Incorporated 70 Cantiague Rock Road Hicksville, New York 11801
Method of aspiration	Suction through tubing attached to dental office Hi-Vac	Air-driven piston that creates flushing action for rinsing root canals; attached to dental office Hi-Vac
Attached to dental handpiece	No	Yes

Indications for use	The EndoVac® system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.	The RinsEndo is used for root canal irrigation/disinfection.
Single use disposable cannula (tips)	Yes	Yes
Biocompatibility	Complies with ISO 10993 standards	Complies with ISO 10993 standards
Sterilization	Autoclavable Master Delivery Tip, Multi-Port Adapter, Handpiece and Finger-Piece	Autoclavable handpiece

Non-Clinical Performance Data.

The performance of EndoVac® Apical Negative Pressure Irrigation System has been verified utilizing the following standards:

- ISO 10993-1 Biological Evaluation of Medical Devices - Evaluation and Testing
- ISO 10993-5:2009 Biological evaluation of medical devices -- Tests for in vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices -- Tests for irritation and skin sensitization
- AAMI TIR 12: 2010 Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Manufacturers
- ANSI/AAMI ST:79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI TIR 39:2009 Guidance on selecting microbial challenge and inoculation sites for sterilization validation of medical devices
- ISO 17665-1:2006 Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- Internal method for autoclave life testing of reusable products

Clinical Performance Data.

SybronEndo has not performed human clinical evaluations for EndoVac® Apical Negative Pressure Irrigation System. A summary of published literature has been included in order to support the safety and efficacy of the device.

Conclusion as to Substantial Equivalence

The similarities in design, function, safety and intended use of EndoVac® Apical Negative Pressure Irrigation System with the legally marketed device RinsEndo dental handpiece (K052271) provide evidence that these devices are substantially equivalent. The data provided in this submission support the substantial equivalence of the EndoVac® Apical Negative Pressure Irrigation System to the predicate, RinsEndo dental handpiece (K052271).