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

May 6, 2016

Sybron Dental Specialties
Ms. Wendy Garman
VP, Regulatory Affairs
1717 W. Collins Ave.
Orange, California 92867

Re: K152956
Trade/Device Name: Pulp Canal Sealer and Pulp Canal Sealer EWT
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: March 7, 2016
Received: March 8, 2016

Dear Ms. Garman:

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 yours,

for 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

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)*
K152956

Device Name
Pulp Canal Sealer and Pulp Canal Sealer EWT

Indications for Use *(Describe)*
Pulp Canal Sealer and Pulp Canal Sealer EWT are used for permanent obturation of the root canal space with the aid of obturating points in accordance with ISO 6876 for Dental Root Canal Sealing materials.

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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SECTION 5. 510(k) SUMMARY FOR
Pulp Canal Sealer and Pulp Canal Sealer EWT

Pulp Canal Sealer and Pulp Canal Sealer EWT

1. Submitter Information**:**

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

Contact Person: Heather Crilly
Telephone Number: 909-962-5664
Fax Number: 909-962-5694

Date Prepared: May 05, 2016

2. Device Name:

- Proprietary Name: Pulp Canal Sealer and Pulp Canal Sealer EWT
- Classification Name: Root Canal Filling Resin
- CFR Number: 872.3820
- Device Class: II
- Product Code: KIF

3. Predicate Device:

The Proposed Pulp Canal Sealer and Pulp Canal Sealer EWT are substantially equivalent to the legally marketed device Pulp Canal Sealer/Pulp Canal Sealer EWT (K945244) cleared on December 29, 1994, product code KIF.

4. Description of Device:

Pulp Canal Sealer and Pulp Canal Sealer EWT are used for permanent obturation of the root canal space with the aid of obturating points in accordance with ISO 6876 for Dental Root Canal Sealing materials. They are Zinc Oxide/Eugenol root canal sealants. The products are made up of two separate components, a powder base and a liquid catalyst, to form the final device. The liquid catalyst is the same formulation for both products. Pulp Canal Sealer is a fast setting material, while Pulp Canal Sealer EWT features an extended work time of greater than 6 hours on the pad.

5. Statement of Indications for Use:

Pulp Canal Sealer and Pulp Canal Sealer EWT are used for permanent obturation of the root canal space with the aid of obturating points in accordance with ISO 6876 for Dental Root Canal Sealing materials.

6. Description of Substantial Equivalence

Technological Characteristics:

The **powder base** formulation of the Proposed Pulp Canal Sealer and the predicate device, Pulp Canal Sealer/Pulp Canal Sealer EWT (K945244), are very similar. The only difference being the formula range of the ingredient Thymol Iodide in the Pulp Canal Sealer product. The predicate Pulp Canal Sealer contains a higher limit of Thymol Iodide, while the Proposed Pulp Canal Sealer contains a lower formula range. The Proposed Pulp Canal Sealer EWT powder base remains unchanged.

The **liquid catalyst** is the same formulation used for both the Proposed Pulp Canal Sealer and Pulp Canal Sealer EWT and the predicate device, Pulp Canal Sealer/Pulp Canal Sealer EWT (K945244). The liquid catalyst remains unchanged.

Pulp Canal Sealers are intended to fill the microscopic gaps between the root canal filler/obturator product (i.e. Gutta Percha) and the root canal wall. The powder base contains Zinc Oxide and the liquid catalyst contains Eugenol. The base and catalyst are combined and mixed into a homogenous paste which is then placed directly into the root canal as a thin layer. Once the Zinc Oxide and Eugenol are mixed, the Eugenol is consumed and converted into a solid complex. The sealer paste will set due to a chelation reaction between the Zinc Oxide and Eugenol. The hardening of the thin layer occurs within the root canal in the presence of moisture.

Thymol Iodide has no significance within the chemical reaction that takes place in the actual formation of the root canal sealant. The only known effect of the addition of Thymol Iodide is that it may accelerate set times. The difference between the predicate limit and the proposed limit of Thymol Iodide is a minor change, and no effect to the formulation could be measured or recorded.

The formulation utilizing the lowered formulation range of Thymol Iodide has been on the market for a number of years in Europe. Based on post market data and design verification testing, the performance characteristics of this material results are substantially equivalent to those of the predicate. The slight variation in Thymol Iodide does not change the performance characteristics of the device.

7. Non-Clinical Performance Data:

Verification and validation activities were performed in accordance with design control requirements as specified in 21 CFR 820.30, ISO 13485:2012 Medical Devices- Quality Management Systems, and ISO 6876 Dental – Root Canal Sealing Materials, and the results demonstrated substantial equivalence to the predicate. The Tables 5.1 and 5.2 below depict the modifications associated with Pulp Canal Sealer and Pulp Canal Sealer EWT.

Non-clinical performance data included testing for Consistency, Solubility, Work/Set Time, Film Thickness, and Biocompatibility testing (refer to Table 6.2). The data analyzed from the various tests substantiate that the Proposed Pulp Canal Sealer and Pulp Canal Sealer EWT are substantially equivalent to the predicate devices. The following standard was utilized for non-clinical performance testing of the proposed:

- ISO 6876:2012 Dentistry – Root canal sealing materials

Clinical Performance Data:
Clinical performance testing has not been performed for Pulp Canal Sealer and Pulp Canal Sealer EWT.

Table 5.1: Predicate Pulp Canal Sealer/Pulp Canal Sealer EWT (K945244) and Proposed Pulp Canal Sealer and Pulp Canal Sealer EWT Device Comparison Table

Element	Predicate Device- Pulp Canal Sealer/Pulp Canal Sealer EWT (K945244)	Proposed Pulp Canal Sealer and Pulp Canal Sealer EWT (K152956)
Trade Name	Pulp Canal Sealer/Pulp Canal Sealer EWT	Pulp Canal Sealer and Pulp Canal Sealer EWT
Target Users	Licensed dental professionals	Licensed dental professionals
Device Description	Pulp Canal Sealer and Pulp Canal Sealer EWT are used for permanent obturation of the root canal space with the aid of obturating points in accordance with ISO 6876 for Dental Root Canal Sealing materials.	The Proposed Pulp Canal Sealer and Pulp Canal Sealer EWT are used for permanent obturation of the root canal space with the aid of obturating points in accordance with ISO 6876 for Dental Root Canal Sealing materials.
Common Name	Root Canal Sealer	Root Canal Sealer
Classification Name	Root Canal Filling Resin per 21 CFR § 872.3820	Root Canal Filling Resin per 21 CFR § 872.3820
Class	II	II
Product Code	KIF	KIF
Powder Base Formula for Pulp Canal Sealer (PN 24875) Only	Contains: Thymol Iodide	Contains: Decreased range of Thymol Iodide
Powder Base Formula for Pulp Canal Sealer EWT(PN 24746) Only	Formula per K945244	No Change from K945244
Catalyst Formula (Same for both products)	Formula per K945244	No Change from K945244
Manufacturing Location	Romulus, MI (USA)	Scafati, Italy
Legal Manufacturer/Spec Developer	Kerr Corporation Romulus, MI	SybronEndo Glendora, CA
Packaging	Powder: Cap – Polypropylene Bottle – Polystyrene Liquid: Cap – Low Density Polyethylene Bottle – Polypropylene	Powder: Cap – Polypropylene Bottle – Polystyrene Liquid: Cap –Low Density Polyethylene Bottle – Polypropylene

Table 5.2: Predicate Pulp Canal Sealer/Pulp Canal Sealer EWT (K945244) and Proposed Pulp Canal Sealer and Pulp Canal Sealer EWT Physical and Mechanical Properties Comparison

PHYSICAL & MECHANICAL PROPERTIES COMPARISON				
	Predicate Device (K945244)		**Proposed Device (K152956)**	
Element	**Pulp Canal Sealer**	**Pulp Canal Sealer EWT**	**Pulp Canal Sealer**	**Pulp Canal Sealer EWT**
Chemistry of Setting Reaction	Chelation between zinc oxide & eugenol		Chelation between zinc oxide & eugenol	
Consistency	29 mm	28.5 mm	28 mm	25 mm
Solubility	0.09%	0.47%	0.34%	0.36%
Work/Set Time	**Work Time:** > 45 Minutes **Set Time**: < 60 Minutes Max	**Work Time:** > 6 Hours **Set Time:** < 2 Hours Max	**Work Time:** > 45 Minutes **Set Time**: < 60 Minutes Max	**Work Time:** > 6 Hours **Set Time:** < 2 Hours Max
Film Thickness (µm)	22.6 µm	23.6 µm	20.66 µm	33.87 µm
Safety	Pass		Pass	

Conclusion as to Substantial Equivalence:

Pulp Canal Sealer/Pulp Canal Sealer EWT (K945244) is an existing device which was granted FDA market clearance in 1994. Sybron Dental Specialties seeks only to slightly modify the existing device cleared under K945244. Additionally, the manufacturer name will change to SybronEndo, the device will be produced at a sister facility in Scafati, Italy (Kerr Italia), and the product code will be updated to KIF. Tables 5.1 and 5.2 depict the modifications associated with the Proposed Pulp Canal Sealer and Pulp Canal Sealer EWT.

The film thickness of the proposed device is roughly 10 microns thicker than the predicate device as shown in Table 5.2 above. Table 5.2 demonstrates that the difference in film thickness between the predicate and proposed devices does not affect the substantial equivalence of the subject and predicate devices. The sealer was tested to meet ISO 6876 standards which state that a sealer shall have a film thickness of not more than 50 µm. The Proposed Pulp Canal Sealer and Pulp Canal Sealer EWT is still below the maximum 50 µm allowance and will flow sufficiently to fill the voids, as the film thickness remains within the proper specifications of the ISO standard requirements.

The modification of Pulp Canal Sealer (PN 24875) to lower the formulation range of the ingredient Thymol Iodide, and the move of the manufacturing location to Scafati, Italy do not affect the intended use nor does it alter the fundamental scientific technology of the device. The nonclinical testing demonstrates that the Proposed Pulp Canal Sealer and Pulp Canal Sealer EWT perform as well as the predicate device. The Proposed Pulp Canal Sealer and Pulp Canal Sealer EWT are substantially equivalent to the predicate Pulp Canal Sealer/Pulp Canal Sealer EWT (K945244).