DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 27, 2016

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

Re: K153067
Trade/Device Name: Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress)
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: May 20, 2016
Received: June 7, 2016

Dear Wendy 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,

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)*
K153067

Device Name
Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress)

Indications for Use *(Describe)*
The Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) is used for permanent obturation of the root canal space with the aid of obturating points.

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 6. 510(k) SUMMARY FOR THE TUBLI-SEAL PRODUCT LINE (TUBLI-SEAL/ TUBLI-SEAL XPRESS/TUBLI-SEAL EWT/TUBLI-SEAL EWT XPRESS)

K153067

1. Submitter Information**:**

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

Contact Person: Wendy Garman
Telephone Number: 909.962.5666
Fax Number: 909.962.5694

Date Prepared: July 14, 2016

2. Device Name:

- Proprietary Name: Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress)
- Classification Name: Resin, Root Canal Filling
- CFR Number: 872.3820
- Device Class: II
- Product Code: KIF

3. Predicate Device:

The Proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/ Tubli-Seal EWT Xpress) is substantially equivalent to the legally marketed devices Tubli-Seal/Tubli-Seal EWT (K942393, cleared on June 10, 1994), product code KIF.

4. Description of Device:

The Proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/ Tubli-Seal EWT/ Tubli-Seal EWT Xpress) is a Zinc Oxide Eugenol root canal sealer to be used for permanent obturation of the root canal space in conjunction with obturating points. It is a two-part, base/accelerator, paste/paste system that is mixed in equal portions. Then the mixture is carried to the root canal with endodontic obturation points, or directly dispensed in the root canal depending on delivery method, e.g. tube or dual-barrel syringe. The product is available in two (2) working times, Regular and Extended Work Time (EWT) for both delivery options of tubes or dual-barrel syringes.

The proposed is available packaged in tubes (Tubli-Seal and Tubli-Seal EWT) and dual-barrel syringes (Tubli-Seal Xpress and Tubli-Seal EWT Xpress) used with single-use automix tips. The tubes are dispensed onto a mixing pad, hand mixed and then applied to the canal with an endodontic point. Tubli-Seal Xpress has the same formulation and indications for use as Tubli-Seal, and Tubli-Seal EWT Xpress has the same formulation and indications for use as Tubli-Seal EWT. The proposed syringe-delivery products are

branded as “Tubli-Seal Xpress” and “Tubli-Seal EWT Xpress” and offer the convenience of single-use automix tips that remove the need for hand mixing. The dual-barrel and single-use automix tips allow the dental professional to deliver the desired volume of Tubli-Seal Xpress or Tubli-Seal EWT Xpress directly into the prepped root canal.

Table 6.1 Description of Accessories used with the proposed Tubli-Seal Xpress and Tubli-Seal EWT Xpress

Accessories Used with Tubli-Seal Xpress and Tubli-Seal EWT Xpress	Manufacturer of Accessory
Dual-barrel syringe	Sulzer Mixpac AG Ruetistrasse 7 Haag Sankt gallen, Switzerland 9469
Auto-mix tips	Sulzer Mixpac AG Ruetistrasse 7 Haag Sankt gallen, Switzerland 9469

5. Statement of Indications for Use:

The Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) is used for permanent obturation of the root canal space with the aid of obturating points.

6. Summary of Technological Characteristics:

The **base** formulation of the proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) and the predicate devices, Tubli-Seal/Tubli-Seal EWT (K942393), remain unchanged.

The **accelerator** formulations of the proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) and the predicate devices, Tubli-Seal/Tubli-Seal EWT (K942393), are very similar, with the only differences being the adjustment of resin and the addition of a new, yet substantially equivalent resin, the adjustment of the reactive solvent and filler, and the addition of a new filler/setting accelerator.

The resin change in the proposed device helps enhance the stability and performance. The two resin types are considered substantially equivalent. The changes in reactive solvent and filler were to accommodate the addition of a new resin type and filler/setting accelerator in the proposed accelerator formulation. The slight addition of a new filler/setting accelerator to the proposed accelerator is added during manufacturing to accelerate the set time based on in-process set-time testing to meet specification. The addition of the setting accelerator may not be necessary if in-process set-time testing meets specification. The filler and resins have no significance within the chemical reaction that takes place in the actual formation of the root canal sealant.

The mixing of the base and accelerator, in the presence of moisture that is in root canal, causes the sealer to harden. Trace amounts of water initiates the chelation reaction between the accelerator and base that results in a solid fill. The Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) is intended to

fill the microscopic gaps between root canal filler and canal walls. The slightly modified formulation for the proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/ Tubli-Seal EWT/Tubli-Seal EWT Xpress) has successfully been on the EU market for several years. Performance testing on stability, work time, set time and slump were performed on the modified formula to validate that the proposed products meet the current product specifications and are substantially equivalent to the predicate.

7. Non-Clinical Performance Data:

Verification activities were performed in accordance with design control requirements as specified in 21 CFR 820.30, ISO 13485 Medical Devices- Quality Management Systems, and ISO 6876:2012 Dental – Root Canal Sealing Materials, and the results demonstrated substantial equivalence to the predicate Tubli-Seal/ Tubli-Seal EWT (K942393). Performance testing on stability, work time, set time and slump were performed on the modified formula to validate that the proposed products meet the current product specifications and are substantially equivalent to the predicate. Table 6.2 below depicts the modifications associated with the predicate and proposed devices.

8. Summary of Performance Testing

Performance Testing – Bench

Performance testing for the proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) included testing for Consistency (Flow), Film Thickness, Solubility and Radiopacity per ISO 6876:2012 – Dentistry – Root Canal Sealing Materials (See Table 6.2).

The proposed accelerator formulation for Tubli-Seal was considered the “worst-case” scenario for biocompatibility and performance testing since its accelerator formulation contains two additional components that are not contained in the predicate devices or proposed Tubli-Seal EWT formulation. The “worst-case” scenario’s performance and biocompatibility testing results are directly applicable to the proposed Tubli-Seal EWT since the formulation, intended use, and performance are very similar. Therefore, the predicate and proposed test results are substantially equivalent to support intended use.

In the Physical and Mechanical Properties of Table 6.2, the film thickness has a 4.57 micron (μm) difference between the predicate and proposed devices. This difference does not affect the substantial equivalence of the subject and predicate devices. The sealer was tested to meet ISO 6876:2012 standard, which states that a sealer shall have a film thickness of not more than 50 μm. The proposed Tubli-Seal product line (Tubli-Seal/ Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) is below the maximum 50 μm allowance. Therefore, the predicate and proposed sealers will flow sufficiently into the root canal and adapt to canal shape to fill voids.

The predicate and proposed devices produced Solubility and Disintegration results of 0.70% and 0.46%, respectively. According to ISO 6876:2012, the solubility may not exceed 3.0%. This data shows no substantial difference between the predicate and proposed devices according to ISO 6876:2012.

The data analyzed from the various tests substantiate that the proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) is substantially equivalent to the predicate Tubli-Seal/Tubli-Seal EWT (K942393).

9. Substantial Equivalence:

Tubli-Seal/Tubli-Seal EWT (K942393) are existing devices which were granted market clearance by FDA in 1994. Sybron Dental Specialties, on behalf of SybronEndo, seeks only to slightly modify the formula and the Indications for Use statement of the existing devices cleared under K942393. The proposed Indications for Use statement will specifically mention the use of "obturation points" to clearly describe the device's use as it is common practice for obturation points to be used with endodontic sealers.

Additionally, the device would be produced at a sister facility in Scafati, Italy (Kerr Italia); and the manufacturer name will change to SybronEndo. The proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) has been on the market in the EU for a number of years without incident.

According to ISO 6876:2012, the proposed device performs as well as the legally marketed predicate device (K942393). Therefore, the proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) is considered to be substantially equivalent to the predicate device.

Table 6.2 depicts the comparison of performance and mechanical properties and modifications associated with the proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress).

Table 6.2: Predicate Tubli-Seal/Tubli-Seal EWT (K942393) and the proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) Comparison Table

Element	**Predicate Device- Tubli-Seal/ Tubli-Seal EWT (K942393)**	**Proposed Device- Tubli-Seal product line (Tubli-Seal/ Tubli-Seal Xpress/ Tubli-Seal EWT/ Tubli-Seal EWT Xpress)**
Trade Name	Tubli-Seal/Tubli-Seal EWT	Tubli-Seal/Tubli-Seal Xpress/ Tubli-Seal EWT/Tubli-Seal EWT Xpress
Target Users	Licensed dental professionals	Licensed dental professionals
Indications for Use	Tubli-Seal EWT, a paste/paste base and catalyst formulation, is intended for permanent obturation of pulp space in teeth requiring root canal treatment.	The Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) is used for permanent obturation of the root canal space with the aid of obturating points.
Device Description	Tubli-Seal/Tubli-Seal EWT (K942393) is a Zinc Oxide Eugenol root canal sealer to be used for permanent obturation of the root canal space in conjunction with obturating points. It is a two-	The Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) is a Zinc Oxide Eugenol root canal sealer to be used for permanent obturation of the root canal space in conjunction with obturating points.

	part, base/accelerator, paste/paste system. The two-part system is packaged in tubes. The product is available in two (2) working times, Regular and Extended Work Time (EWT).	It is a two-part, base/accelerator, paste/paste system. The two part system is packaged in tubes that are hand mixed, then placed into the prepped root canal, or in a dual-barrel syringe (Tubli-Seal Xpress and Tubli-Seal EWT Xpress) that does not require hand mixing. The product is available in two (2) working times, Regular and Extended Work Time (EWT).
Common Name	Root Canal Sealer	Root Canal Sealer
Classification Name	Resin, Root Canal Filling per CFR § 872.3820	Resin, Root Canal Filling per CFR § 872.3820
Class	II	II
Product Code	KIF	KIF
Base Formula for Tubli-Seal/ Tubli-Seal EWT/ Tubli-Seal Xpress	Formula per K942393	No Change from K942393
Accelerator Formula for Tubli-Seal/ Tubli-Seal Xpress	Contains: • Resin • Solvent • Filler	Proposed formulation changes: • Decreased amount of Resin that is currently in formation • Second resin added to formulation (total percentage of two (2) resins does not exceed current percentage) • Decreased amount of Solvent currently in formulation • Decreased amount of Filler currently in formulation • Setting Accelerator may be added to the formulation as needed during manufacturing to meet set time specification
Accelerator Formula for Tubli-Seal EWT/ Tubli-Seal EWT Xpress	Contains: • Resin • Solvent • Matrix Fluid	Proposed formulation changes: • Decreased amount of Resin that is currently in formulation • Second resin added to formulation (total percentage of two (2) resins does not exceed current percentage)
Legal Manufacturer/ Specification Developer	Kerr Corporation 28200 Wick Road Romulus, MI 48174 USA	SybronEndo 1332 S. Lone Hill Ave. Glendora, CA 91740 USA

Manufacturing Location	Kerr Corporation 28200 Wick Road Romulus, MI 48174 USA	Kerr Italia, S.R.L. Via Passanti, 332 Scafati Salerno, I-84018 ITALY
Packaging	Laminate Tubes	Laminate Tubes and Polypropylene dual-barrel syringes used with single-use automix tips.
Physical and Mechanical Properties		
Form	Two Pastes (Accelerator & Base)	Two Pastes (Accelerator & Base)
Mix Ratio	Equal Volumes	Equal Volumes
Consistency (Flow)	29 mm	28mm
Film Thickness	13.04 µm	17.61 µm
Solubility and Disintegration	0.70%	0.46%
Radiopacity	5 mm Al	6 mm Al

10. Conclusion as to Substantial Equivalence:

    The slight modifications of the Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/ Tubli-Seal EWT/Tubli-Seal EWT Xpress) accelerator formulations, Indications for Use statement and the move of the manufacturing location to Scafati, Italy (Kerr Italia) does not affect the intended use of the device nor does it alter the fundamental scientific technology of the device.

    The nonclinical testing demonstrates that the Proposed Tubli-Seal product line (Tubli-Seal/ Tubli-Seal Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) performs as well as the predicate device based on the specifications set by ISO 6876:2012 testing requirements. The Proposed Tubli-Seal product line (Tubli-Seal/Tubli-Seal Xpress/ Tubli-Seal EWT/Tubli-Seal EWT Xpress) is substantially equivalent to the predicate Tubli-Seal/ Tubli-Seal EWT (K942393).