



Food and Drug Administration  
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April 14, 2016

Sybron Dental Specialties  
Jennifer Dzidrums  
1332 S. Lone Hill Ave.  
Glendora, CA 91740

Re: K152959-S001

Trade/Device Name: SEALAPEX/ SEALAPEX XPRESS

Regulation Number: 21 CFR 872.3820

Regulation Name: Resin, Root Canal Filling

Regulatory Class: Class II

Product Code: KIF

Dated: March 07, 2016

Received: March 08, 2016

Dear Jennifer Dzidrums:

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,

**Erin I. Keith -S**

Erin 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

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

## Indications for Use

510(k) Number *(if known)*

Device Name

Sealapex/Sealapex Xpress

Indications for Use *(Describe)*

Sealapex/ Sealapex Xpress is a calcium hydroxide, polymeric resin, root canal filling material that is used in conjunction with gutta percha or silver endodontic 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 SEALAPEX/ SEALAPEX XPRESS**



**Sealapex/ Sealapex Xpress**

1. Submitter Information:

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

Contact Person: Jennifer Dzidrums  
Telephone Number: 909-962-5650  
Fax Number: 909-962-5694

Date Prepared: April 8, 2016

2. Device Name:

- Proprietary Name: Sealapex and Sealapex Xpress
- Classification Name: Resin, Root Canal Filling
- CFR Number: 872.3820
- Device Class: II
- Product Code: KIF

3. Predicate Device:

The proposed Sealapex/Sealapex Xpress is substantially equivalent to the legally marketed device, Sealapex 4 (K010940), cleared on June 20, 2001, product code KIF.

4. Description of Device:

Sealapex/Sealapex Xpress is a non-eugenol, radiopaque, calcium hydroxide polymeric resin root canal filling material. It is indicated for use as a root canal sealing and filling material, and is used during an endodontic procedure to seal off the prepared root canal apical foramen and tubules from blood, exudates, and infection. The proposed is a two-part, base/catalyst – 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 proposed is available packaged in tubes (Sealapex) and dual-barrel syringes (Sealapex 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. Sealapex Xpress has the same formulation and indications for use as Sealapex, but is branded as “Sealapex Xpress” since it offers 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 Sealapex Xpress directly into the prepped root canal.

**Table 6.1 Description of Accessories used with the Proposed Sealapex Xpress**

Accessories Used with Sealapex 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:

Sealapex/Sealapex Xpress is a calcium hydroxide, polymeric resin, root canal filling material that is used in conjunction with gutta percha or silver endodontic points.

6. Technological Characteristics:

Sealapex/Sealapex Xpress is intended to fill the microscopic gaps between the canal filler/obturator and canal walls. Reactive components that let Sealapex/Sealapex Xpress sealer set in root-canal are Calcium Oxide in base paste and Salicylate moieties in accelerator (catalyst) paste. Material hardens upon mixing of the base and accelerator pastes in the presence of moisture in the root canal.

The **paste base** formulation of the proposed Sealapex/Sealapex Xpress and the predicate device, Sealapex 4 (K010940), is very similar, the only difference being an increase in the amount of Resin and Titanium Dioxide, along with a slight addition of a Silica in the proposed Sealapex/Sealapex Xpress base formulation.

The **paste catalyst** formulation of the proposed Sealapex/Sealapex Xpress and the predicate device, Sealapex 4 (K010940), is very similar, the only difference being a decrease in amount of filler, a decrease in Titanium Dioxide, along with the slight addition of a Silica in the proposed Sealapex/Sealapex Xpress catalyst formulation.

Titanium Dioxide (USP) is a common non-toxic white pigment approved by FDA as a food additive, and the minor change does not affect performance or biocompatibility of the paste.

Fumed silica filler serves as a rheological modifier. It does not participate in the setting reaction. Both fillers in the proposed base and catalyst formulations are similar in physical characteristics and surface treated to make the filler particle more hydrophobic and to improve the compatibility with the formulation.

The Resin is an inert, water-insoluble material that helps thicken the paste and does not participate in setting reaction. The slight increase in the amount of Resin should stabilize the consistency of the paste and does not adversely affect the equivalence and performance of the product.

The slightly modified formulation for the proposed Sealapex/ Sealapex 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 Sealapex 4 (K010940).

7. Non-Clinical Performance Data:

Verification activities were performed in accordance with design control requirements as specified in 21 CFR 820.30 and ISO 13485 Medical Devices- Quality Management Systems and the results demonstrated substantial equivalence to the predicate.

8. Summary of Performance Testing

Performance Testing –  
Bench

Performance testing for the proposed Sealapex/ Sealapex Xpress included testing for Consistency (Flow), Film Thickness, and Radiopacity per ISO 6876:2012 – Dentistry – Root Canal Sealing Materials.

In the Physical and Mechanical Properties of Table 6.2, the film thickness has a 13.5 micron ( $\mu\text{m}$ ) 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  $\mu\text{m}$ . The proposed Sealapex and Sealapex Xpress are below the maximum 50  $\mu\text{m}$  allowance. Therefore, the predicate and proposed sealers will flow sufficiently into the root canal and adapt to canal shape to fill voids.

Table 6.2 displays both an internal and the ISO 6876:2012 test method for determining Flow. The internal test method for Flow differs from the current ISO 6876:2012 test procedure due to the amount of sample used for testing.

The predicate and proposed devices produced Flow results of 48.5 mm and 51.0 mm, respectively, based on internal test methods. This data shows no substantial difference between the predicate and proposed devices. Per ISO 6876:2012, the predicate and proposed devices show no substantial difference based on Flow test results of 22.8 mm and 23.1 mm, respectively.

The data analyzed from the various tests substantiate that the proposed Sealapex/ Sealapex Xpress is substantially equivalent to the predicate Sealapex 4 (K010940).

9. Substantial Equivalence:

Sealapex 4 (K010940) is an existing device which was granted market clearance by FDA in 2001. Sybron Dental Specialties, on behalf of SybronEndo, seeks only to slightly modify the formula of the existing device cleared under K010940. Additionally, the device would be produced at a sister facility in Scafati, Italy; and the manufacturer name will change to SybronEndo.

Table 6.2 depicts the comparison of performance and mechanical properties and modification associated with the proposed Sealapex/Sealapex Xpress.

**Table 6.2: Predicate Sealapex 4 (K010940) and Proposed Sealapex/Sealapex Xpress Comparison Table**

<b>Element</b>	<b>Predicate Device- Sealapex 4</b>	<b>Proposed Sealapex/Sealapex Xpress</b>
510(k)	K010940	K152959
Trade Name	Sealapex 4	Sealapex and Sealapex Xpress
Target Users	Licensed dental professionals	Licensed dental professionals
Indications for Use	Sealapex 4 is a calcium hydroxide, polymeric resin, root canal filling material that is used in conjunction with gutta percha or silver endodontic points	Sealapex/Sealapex Xpress is a calcium hydroxide, polymeric resin, root canal filling material that is used in conjunction with gutta percha or silver endodontic points
Device Description	Sealapex 4 is a non-eugenol, radiopaque, calcium hydroxide polymeric resin root canal filling material. Sealapex 4 is a two-part, base/catalyst – paste/paste system. The two-part system is packaged in tubes that is hand mixed, then placed into the prepped root canal.	Sealapex/Sealapex Xpress is a non-eugenol, radiopaque, calcium hydroxide polymeric resin root canal filling material. Sealapex/Sealapex Xpress is a two-part, base/catalyst – 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 (Sealapex Xpress) that does not require hand mixing.
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	Contains: Resin Titanium Dioxide	Contains: Increased range of Resin Increased range of Titanium Dioxide Added: Silica
Catalyst Formula	Contains: Filler Titanium Dioxide	Contains: Decreased range of Filler Increased range of Titanium Dioxide Added: Silica
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.
<b>Physical and Mechanical Properties</b>		
Form	Two Pastes (Catalyst & Base)	Two Pastes (Catalyst & Base)
Mix Ratio	Equal Volumes	Equal Volumes
Work Time @ 37°C (98.6° F), 100% RH	> 60 minutes	> 60 minutes
Setting time @ 37°C (98.6° F), 100% RH	< 24 hours	< 24 hours
Consistency (Flow) per Internal Test Method and Specification	48.5 mm	51.0 mm
Consistency (Flow) per ISO 6876:2012 Method	22.8 mm	23.1 mm
Film Thickness	20.3 µm	33.85 µm
Solubility and Disintegration	N/A	N/A
Radiopacity	> 3.3mm Al	6.0 mm Al

10. Conclusion as to Substantial Equivalence:

The slight modifications of Sealapex/ Sealapex Xpress base and catalyst formulations and the move of the manufacturing location to Scafati, Italy 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 Sealapex/Sealapex Xpress performs as well as the predicate device based on the specifications set by ISO 6876:2012 testing requirements. The proposed Sealapex/Sealapex Xpress are substantially equivalent to the predicate Sealapex 4 (K010940).