Septodont
Jaimie Woodruff
RA Supervisor
416 South Taylor Avenue
Louisville, Colorado 80027

February 13, 2018

Re: K172839
Trade/Device Name: Endosolv
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: September 28, 2017
Received: September 29, 2017

Dear Jaimie Woodruff:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172839

Device Name
ENDOSOLV

Indications for Use *(Describe)*
Root canal sealers solvent when canal retreatment is required.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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004_Indications for Use Statement

5 510(k) Summary K172839

Traditional 510(k) Summary

I. MANUFACTURER:

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Date Prepared: September 8, 2017

II. DEVICE

Trade/Proprietary Name:	ENDOSOLV
Common Name:	Resin, Root Canal Filling
Classification Name:	Root Canal Filling Resin (21 CFR 872.3820)
Regulatory Class:	II
Product Code:	KIF

III. PREDICATE DEVICE(S)

K980633 ENDOSOLV E	Product code: KIF *(predicate device)*
K780003 ENDOSOLV E	Product code: KJJ *(reference device)*

IV. Device Description

ENDOSOLV (new device, K172839/S001) is a solvent used for eugenate-type or phenolic resin-based endodontic cements in the context of endodontic retreatment. This solvent is able to soften conventional zinc oxide eugenol cements and phenolic resin type

sealers in the context of endodontic retreatment. It is indicated for use as a root canal sealer solvent when canal retreatment is required.

Despite being highly successful, some endodontic treatments do not respond to initial therapy for different reasons and, hence, retreatment, also called canalar desobturation, becomes necessary. Many techniques are available for endodontic retreatment including the use of a solvent.

ENDOSOLV (new device, K172839/S001) composition consists of ethyl acetate, amyl acetate and thymol. Ethyl acetate and amyl acetate are the two main components of the formulation that are effective in dissolving zinc oxide-eugenol-based and resin based filling material.

V. Indication for Use

ENDOSOLV (new device, K172839/S001): Root canal sealers solvent when canal retreatment is required.
ENDOSOLV E (predicate device, K980633): Root canal filling remover for zinc-oxide eugenol–based materials.

The Indication for Use statement for ENDOSOLV (new device, K172839/S001) is not identical to the predicate devices; however, the differences do not alter the intended therapeutic use nor do they affect the safety and effectiveness of the device in comparison to the predicate device.

ENDOSOLV (new device, K172839/S001) in comparison to ENDOSOLV E (predicate device, K980633) does not limit the intended use of the root canal filling remover to zinc-oxide eugenol based material. ENDOSOLV (new device, K172839/S001) widens the intended use scope of the product to ‘root canal sealers solvent when canal retreatment is required. This new indication for use includes both the conventional zinc oxide eugenol cement and resin type sealers in context of endodontic retreatment.

VI Comparison of Technological Characteristics with the Predicate Device

Ethyl acetate and amyl acetate are the two main components of the formulation in ENDOSOLV (new device, K172839/S001) that are effective in dissolving zinc oxide-eugenol-based and resin based filling materials.

The predicative devices ENDOSOLV E (reference device, K780003) and ENDOSOLV E (predicate device, K980633) the only difference between the two devices was the removal of solvent, trichloroethane replaced by tetrachloroethylene in ENDOSOLV E (predicate device, K980633). The formula was changed because trichloroethane is banned in France.

Next, the ENDOSOLV (new device, K172839/S001) in relation to ENDOSOLV E (predicate device, K980633) the major difference is the ingredient tetrachloroethylene

which has been replaced by Ethyl Acetate. The reason for the change is Tetrachloroethylene is due to concerns of toxicity. In addition, overall formulation quantities has been modified minimally between the predicate devices and new device. ENDOSOLV (new device, K172839/S001) has been adjusted to account for the substitutional change in solvent from tetrachloroethylene to Ethyl Acetate.

VII Performance Data

Biocompatibility Testing

The biocompatibility evaluation for ENDOSOLV (new device, K172839/S001; based on ISO 10993 standards) are:

Type of study	Study number	Guideline	Study site	Main findings	Reference
Cytotoxicity	1752100	ISO 10993-5 (2009)	Envigo	Not cytotoxic	(Envigo and Markus Roth, 2016)
Hypersensitivity	SMKiso-PH-16/0032	ISO 10993-10 (2010)	Phycher Biodevelopment	Not sensitizer	(Colas, 2016)
Irritation	MJ-PH-16/0032	ISO 10993-10 (2010)	Phycher Biodevelopment	Negligible irritation	(Colas and Phycher, 2016)
Pulp and dentin test	NA	NA	NA	Not in contact.	NA

Performance Testing

Two studies were performed in accordance to ISO 6876:2012 by Septodont in order to compare the effectiveness of ENDOSOLV (new device, K172839/S001) in comparison with ENDOSOLV E (predicate device, K980633) and ENDOSOLV R, considered positive control. The literature review revealed the effectiveness of those solvents in their intended indication: soften respectively eugenate-based and phenolic resin based root canal sealer when an endodontic retreatment is necessary (Gambrel et al., 2005;Canakci et al., 2015;Ramzi et al., 2010;Saglam et al., 2013). Purified water is then used as negative control in both assays. Moreover, a sealer was also used as negative control: Acroseal, it is an epoxy-resin based root canal sealer and neither of the solvents is indicated to soften this material. The first assay permits to conclude that ENDOSOLV (new device, K172839/S001) is as effective as ENDOSOLV E (predicate device, K980633) to dissolve eugenate based root canal sealer. Because of the successful results obtained with the new formulation that were comparable to ENDOSOLV E (predicate device, K980633), the intended performance of dissolving eugenate based root canal filling material is confirmed. Please see Table 1 for Summary of Results.

Moreover, the second study permits to demonstrate the performance of ENDOSOLV (new device, K172839/S001) to dissolve resin based root canal filling material. This study showed ENDOSOLV (new device, K172839/S001) results comparable to those

obtained with ENDOSOLV R (*only approved for sale in EU; indication: soften phenolic resin based root canal sealer; voluntary withdrawal of device from EU and Canada for precautionary reasons in order to avoid any risk of exposure of formamide to pregnant patients*), confirming the intended performance of ENDOSOLV (new device, K172839/S001) to dissolve resin based root canal filling material. Please see Table 2 for Summary of results.

Table 1: Softening Time Required to Dissolve Root Canal Sealers

Product	Cement	Softening Time
ENDOSOLV E (predicate device)	Endomethasone SP (eugenate-based root canal sealer)	70sec
ENDOSOLV (new device)	Endomethasone SP (eugenate-based root canal sealer)	47sec
ENDOSOLV E (predicate device)	PCS Pulp Canal Sealer (eugenate-based root canal sealer)	68sec
ENDOSOLV (new device)	PCS Pulp Canal Sealer (eugenate-based root canal sealer)	41sec
ENDOSOLV E (predicate device)	Sealite regular (eugenate-based root canal sealer)	68sec
ENDOSOLV (new device)	Sealite regular (eugenate-based root canal sealer)	141sec
ENDOSOLV E (predicate device)	Acroseal (resin-based root canal sealer)	19min 57sec
ENDOSOLV (new device)	Acroseal (resin-based root canal sealer)	7min 10sec

Table 2: Softening Time Required to Dissolve Resin- Based Root Canal Sealer

Product	Cement	Softening Time (sec)
ENDOSOLV (new device)	resin-based root canal filling material	50
ENDOSOLV E (predicated device)	resin-based root canal filling material	83
ENDOSOLV R (indicated for the dissolution of phenolic based root canal sealers)	resin-based root canal filling material	68
Water (negative control)	resin-based root canal filling material	100

Substantial Equivalence

ENDOSOLV (new device, K172839/S001) in relation to ENDOSOLV E (predicate device, K980633) the major difference is the ingredient tetrachloroethylene which has been replaced by Ethyl Acetate. The reason for the change is Tetrachloroethylene has concerns of toxicity. In addition, overall formulation quantities has been modified minimally between the predicate device and new device. This is due to ENDOSOLV (new device, K172839/S001) has been adjusted to account for the substitutional change in solvent from tetrachloroethylene to Ethyl Acetate.