May 23, 2022

Prevest Denpro Limited
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K212563
Trade/Device Name: CalApex, Calplus, Cerafill RCS, Endoseal, Nanoseal S, Zical Ultra Paste, Zical Ultra Powder/Liquid
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: February 15, 2022
Received: February 28, 2022

Dear Angela Blackwell:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212563

Device Name
Prevest Denpro Root Canal Sealers - CalApex, Calplus, Cerafill RCS, Endoseal, Nanoseal S, Zical Ultra Paste, Zical Ultra Powder/ Liquid

Indications for Use *(Describe)*
CalApex is a calcium hydroxide, polymeric resin, root canal filling material that is used in conjunction with gutta percha or silver endodontic points.

Calplus is a temporary or permanent root canal filling material for use following pulpectomy, or for apexogenesis or apexification.

Cerafill RCS is a MTA (mineral trioxide aggregate) based root canal sealer that provides complete and permanent sealing of root canals. It can be used with or without root canal obturation materials.

Endoseal is 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.

Nanoseal S is indicated in patients for permanent obturations of root canal after vital extirpation or after treatment of pulpal gangrene and temporary filling.

Zical Ultra Paste is used for permanent obturation of the root canal space with the aid of obturating points.

Zical Ultra Powder/Liquid 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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Prevest DenPro Root Canal Sealers (CalApex, Calplus, Cerafill RCS, Endoseal, Nanoseal S, Zical Ultra Paste, Zical Ultra Powder/Liquid)
510K Summary
K212563
May 18, 2022

Name and Address: Prevest Denpro Limited
Export Promotion Industrial Park
Bari Brahmana, Jammu 181133 India
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Email: prevestindia@gmail.com
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Name of device: Prevest Denpro Root Canal Sealers (CalApex, Calplus, Cerafill RCS, Endoseal, Nanoseal S, Zical Ultra Paste, Zical Ultra Powder/Liquid)
Classification Name: root canal sealer
CFR: 21 CFR 872.3820
Primary Product Code: KIF

Submission Contact:
Angela Blackwell
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P.O. Box 718
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Device Description:

CalApex is a non-eugenol, radiopaque, calcium hydroxide polymeric resin root canal filling material. It is a two part, base/catalyst – paste/paste system that is mixed in equal portions. The mixture is then 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.

Calplus can be used as a temporary or permanent root canal filling material.

Cerafill RCS is an endodontic sealer based on MTA, providing a biocompatible and effective root canal filling. It is premixed and pre-loaded in a syringe, which allows a complete filling of the entire root canal including accessory and lateral canals. The product is eugenol-free and will not impede adhesion inside the root canal.

Endoseal is a Zinc Oxide/Eugenol root canal sealant. The product is made up of two separate components, a powder base and a liquid catalyst, to form the final device.

Nanoseal S is a permanent root canal filling material which is silicone based (polydimethylsiloxane). It is cold flowable and is in a dual barrel cartridge.

Zical Ultra Paste is a two-part, base/accelerator, paste/paste system that is mixed in equal portions. The mixture is carried to the root canal with endodontic obturation points. The product comes in a dual barrel cartridge.

Zical Ultra Powder/Liquid is a two-part, powder/liquid system for permanent filling of root canals. The mixture is carried to the root canal with endodontic obturation points.

Indications for Use:

Device Name	Indications
CalApex	CalApex is a calcium hydroxide, polymeric resin, root canal filling material that is used in conjunction with gutta percha or silver endodontic points.
Calplus	Calplus is a temporary or permanent root canal filling material for use following pulpectomy, or for apexogenesis or apexification.
Cerafill RCS	Cerafill RCS is a MTA (mineral trioxide aggregate) based root canal sealer that provides complete and permanent sealing of root canals. It can be used with or without root canal obturation materials.
Endoseal	Endoseal is 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.
Nanoseal S	Nanoseal S is indicated in patients for permanent obturations of root canal after vital extirpation or after treatment of pulpal gangrene and temporary filling.
Zical Ultra Paste	Zical Ultra Paste is used for permanent obturation of the root canal space with the aid of obturating points.
Zical Ultra Powder/Liquid	Zical Ultra Powder/Liquid is used for permanent obturation of the root canal space with the aid of obturating points.

Testing Summary:

CalApex, Cerafill RCS, Endoseal, Nanoseal S, Zical Ultra Paste, and Zical Ultra (powder/liquid) were tested for appearance, flow, film thickness, water solubility, working time, setting time, and disintegration according to protocols based on ISO 6876:2012 and tested for radio-opacity according to a protocol based on ISO 13116:2014. CalPlus was tested for appearance, flow and film thickness according to ISO 6876:2012, and radio-opacity according to ISO 13116: 2014.

Appearance uses a pass/fail criteria set for each device based on the acceptable appearance of each paste, base or catalyst.

Flow test method is based on Section 5.2 of ISO 6876:2012. The CalApex, Cerafill RCS, Endoseal, Nanoseal S, Zical Ultra Paste, and Zical Ultra (powder/liquid) pass criteria is not less than 17mm. The CalPlus pass criteria is 25-28mm.

Film thickness is based on Section 5.5 of ISO 6876:2012. The pass criteria for all subject root canal sealers is not more than 50µm.

Water solubility is based on Section 5.6 of ISO 6876:2012. The pass criteria for all subject root canal sealers is shall not be more than 3% by mass.

Working time is based on Section 5.3 of ISO 6876:2012. The CalAPex pass criteria is 16-18min. The Cerafill RCS, Endoseal, Zical Ultra Paste, and Zical Ultra (powder/liquid) pass criteria is 25-30min. The Nanoseal S pass criteria is 8-10min.

Setting time is based on Section 5.4 of ISO 6876:2012. The CalApex pass criteria is 20-40min. The Cerafill RCS pass criteria is 24 hours. The Endoseal, Zical Ultra Paste, and Zical Ultra (powder/liquid) pass criteria is 45-60min. The Nanoseal S pass criteria is 10-15min.

Disintegration is based on Section 4.3.5 of ISO 6876:2012. The pass criteria for all subject root canal sealers is no evidence of disintegration.

Radio-opacity is based on ISO 13116:2014. The pass criteria for all subject root canal sealers is above or equal to 3 mm when compared with aluminum wedge.

All test results passed and the test method pass criteria meet the criteria in standards. All test reports are included. The bench testing is the same type of test done by the predicate and reference devices. The pass criteria are either the same as the predicate and reference devices (in some cases ISO 6876 sets pass criteria for all root canal sealers) or the pass criteria are tighter than those of the predicate and reference devices. Having a tighter pass criteria would not change the substantial equivalence because the subject devices would also still meet the pass criteria used by the predicate and reference devices.

Shelf life for the root canal sealers is 3 years except for CalApex which is 2 years. Shelf life uses the same testing protocols as the characterization testing which are based on ISO 6876:2012. Pass criteria are the same as for bench testing. The predicate and reference devices use the same ISO standard for their testing but have unknown shelf lives in most cases (Sealapex and MTA Fillapex have a 2 year shelf life).

A biocompatibility assessment according to ISO 10993 was provided for all subject devices.

Predicate Devices: Sealapex K152959, Vitapex K973667, Endoseal MTA K170175, Pulp Canal Sealer K152956, Roeko Seal Root Canal Sealer K983037, Tubliseal K153067

Reference Devices: Apexit K893794 (ingredients), Adseal K042769 (ingedients), Theracal K063237 (ingredients), MTA Fillapex K140247 (ingredients), Dia-Root Bio K200175 (ingredients), GuttaSil K190510 (ingredients)

Substantial Equivalence:

The root canal sealers have similar ingredients to the predicate and reference devices, the same indications for use, and similar physical parameter testing.

Root Canal Sealers from Prevest Denpro

	CalApex K212563 Subject Device	Sealapex K152959 Predicate Device	Apexit K893794 Reference Device	Adseal K042769 Reference Device	Theracal K063237 Reference Device	MTA Fillapex K140247 Reference Device
Product Code	KIF	KIF	KIF	KIF	EJK	KIF
Indications for Use	CalApex 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.	– Permanent obturation following vital pulp extirpation – Permanent obturation following the removal of a gangrenous pulp and placement of intracanal disinfectant dressings – Permanent obturation in cases with external and internal root resorption Apexit Plus is suitable for use in the single cone and lateral condensation technique, as well as in	Adseal is a biocompatible root canal sealer for permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points) Adseal is intended for use by qualified healthcare personnel trained in its use	1. Liner 2. Pulp capping agent	MTA-Fillapex is a root canal sealer intended for the permanent scaling of root canals and may be used in combination with root canal obturation materials.

			all techniques involving heat-softened gutta-percha.			
Device Description	CalApex is a non-eugenol, radiopaque, calcium hydroxide polymeric resin root canal filling material. It is a two part, base/catalyst – paste/paste system that is mixed in equal portions. The mixture is then 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.	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	Apexit is an insoluble, radiopaque calcium hydroxide cement for the permanent obturation of root canals in combination with gutta-percha points. It does not shrink during setting and demonstrates excellent physical and biological properties. Apexit is a two-component system. Base and activator are supplied in double-push syringes with a static mixing device.	Adseal root canal sealer is a two component paste:paste device based upon epoxy-amine resin chemistry. This sealer is easy to mix and adapts closely to the walls of the prepared root canal and provides outstanding long-term dimensional stability with minimal shrinkage upon setting. The device consists of tow components, the epoxy resin paste (Paste A) and the amine containing paste (Paste B); portions of which are mixed prior to insertion into the root canal. This two component	TheraCal is a light-cured resin-based, mineral trioxide aggregate (MTA) filled, liner designed to perform as a barrier and to protect the dental pulpal complex. TheraCal LC's precise placement allows its use in all deep cavity preparations. The light-cured set permits the practitioner immediate placement and condensation of the restorative material. Its proprietary formulation allows for a command set with a visible light curing unit while	MTA Fillapex is a mineral ttioxide aggregate (MTA) and resin toot canal sealer used during endlodontic treatment to permanently fill the canal system following debridement and disinfection. It consists of two component pastes that are combined in a dual barrel syringe for ease of dispensing and consistent dosage. Being hydrophilic in nature, MTA-

		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.		system reacts via an epoxide-amine chemical reaction to cause setting. It may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points). Paste A and Paste B are contained, separately, within the chambers of a two component plastic syringe, packaged with a disposable applicator.	maintaining ease of placement due to thixotropic properties. The proprietary hydrophilic resin formulation creates a stable and durable liner or base.	FILLAPEX is desirable as a root filling material because an isolated dry field is not necessary for use. Moisture does not negatively affect the sealing ability and is required for proper setting. It is used in combinatio n ,with gutta-percha or silver points during root canal obturation.
Compositio n	Base n-ethylene ortho/para toluene sulfonamid e, calcium hydroxide, Portland cement, hydrogenat ed resin, zinc oxide, zinc stearate, pigment, inert ingredients	Base n-ethylene ortho/para toluene sulfonamid e, calcium hydroxide, zinc oxide, zinc stearate Catalyst Methyl salicylate, isobutyl salicylate, 2,2	Calcium salts (hydroxide, oxide, phosphate), hydrogenize d colophony, disalicylate, bismuth salts (oxide, carbonate), highly dispersed silicon dioxide (silanized)	Base Epoxy oligomer resin, ethylene glycol salicylate, bismuth subcarbonate Catalyst Polybutanedio l, Aminobenzoat e, Calcium phosphate,	Portland cement, polyethylen e glycol dimethacryl ate, barium zirconate	Paste A Methyl Salicylate, Butylene Glycol, Colophony, Calcium Tungstate, Fumed Silica Paste B Fumed silica, titanium dioxide, MTA (dicalcium

	Catalyst Ethylene glycol salicylate, butylene glycol, tricalcium phosphate, silica, zinc oxide, bismuth trioxide, zinc stearate, pigment, inert ingredients	dimethylpropane -1,3-diol	and alkyl ester of phosphoric acid.	bismuth subcarbonate		silicate, tricalcium silicate, calcium oxide, tricalcium aluminate), pentaerythritol, rosinate, p-toluenesulfonamide
Form	Two Pastes (Base and Catalyst)	Two Pastes (Base and Catalyst)	Two Pastes (Base and Catalyst)	Two Pastes (Expoxy and Amine)	Light Cured Paste	Two Pastes (Base and Catalyst)
Mix Ratio	Equal Volumes	Equal Volumes	Equal Volumes	Equal Volumes	N/A	Equal Volumes
Film Thickness less than 50µm limit in ISO 6876	Yes	Yes				Yes
Flow according to ISO 6876	>17mm	22.8mm				29mm
Working Time	> 60 minutes	> 60 minutes	3 hours			23 minutes
Setting Time	< 24 hours	< 24 hours				130 minutes
Water Solubility	1.31%	N/A				3%
Radiopacity	6 mm Al	> 3.3mm Al				> 3mm Al
Film thickness, flow, water solubility, working time, and disintegration meet ISO 6876.	Yes	Yes		Yes		Yes

Biocompatibility Assessment According to ISO 10993	Yes	Yes				

	Calplus K212563 Subject Device	Vitapex K973667 Predicate Device
Product Code	KIF	KIF
Indications for Use	Calplus is a temporary or permanent root canal filling material for use following pulpectomy, or for apexogenesis or apexification.	A temporary or permanent root canal filling material for use to stimulate the healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients. Used to promote healing effects and to help prevent bacterial contamination of the canal, as the two ingredients improve the induction effect for hard tissue induction and deposition. To be used as a medicament for the treatment of infected root canals, and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete. For use in the treatment of infected root canals, or following pulpectomy, or for apexogenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha.
Device Description	Calplus can be used as a temporary or permanent root canal filling material.	Vitapex can be used as a temporary or permanent root canal filler material.
Composition	Iodoform, Calcium hydroxide, Silicone Oil, inert ingredients	Iodoform, Calcium hydroxide, Silicone Oil, inert ingredients

Form	Pre-mixed paste	Pre-mixed
Flow	25-28mm	30mm
Film Thickness	<50µm	<50µm
Radiopacity	6 mm Al	>3mm Al
Flow and film thickness meet ISO 6876	Yes	Yes
Biocompatibility Assessment According to ISO 10993	Yes	Unknown

	Cerafill RCS K212563 Subject Device	Endoseal MTA K170175 Predicate Device	DIA-ROOT BIO sealer K200175 Reference Device
Product Code	KIF	KIF	KIF
Indications for Use	Cerafill RCS is a MTA (mineral trioxide aggregate) based root canal sealer that provides complete and permanent sealing of root canals. It can be used with or without root canal obturation materials.	● Permanent obturation of the root canal following vital pulp-extirpation ● Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.	DIA-ROOT BIO Sealer is a MTA (mineral trioxide aggregate) based root canal sealer that provides complete and permanent sealing of root canals. It can be used with or without root canal obturation materials.
Device Description	Cerafill RCS is an endodontic sealer based on MTA, providing a biocompatible and effective root canal filling. It is premixed and pre-loaded in a syringe, which allows a complete filling of the entire root canal including accessory and lateral canals. The product is eugenol-free and will not impede	ENDOSEAL MTA is an endodontic sealer based on MTA, providing a biocompatible and effective root canal filling. It is premixed and pre-loaded in a syringe, which allows a complete filling of the entire root canal including accessory and lateral canals. The product is eugenol-free and will not impede	DIA-ROOT BIO Sealer is a hydraulic material, and a premixed form that does not require mixing. It blocks the root canal by hardening by reacting with water in the oral cavity. It is contained in a waterblocked syringe and corresponds to ISO 6876:2012, Dentistry-Root

	adhesion inside the root canal.	adhesion inside the root canal.	canal sealing materials. DIAROOT BIO Sealer has two models and they are packaged with components; Disposable tip, Silicone cap.
Composition	MTA powder, Zirconium oxide, polyethylene glycol, propylene glycol, fumed silica, bentonite clay, hydroxypropyl methylcellulose, radiopacifiers	MTA powder (Calcium silicates, Calcium aluminates, Calcium aluminoferrite, Calcium sulfates), Bentonite clay, n-methyl-2 pyrrolidone, Hypromellose (alternate name for hydroxypropyl methylcellulose)	Calcium Silicate - Calcium Aluminate - Ytterbium Trifluoride - Zirconium Oxide - Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (fumed silica) - Hydroxypropyl Methylcellulose - Polyethylene glycol 400 - Polyethylene glycol 200 - Sorbitan - White Mineral Oil-
Form	Pre-mixed paste		Pre-mixed paste
Work Time	25-30 minutes		> 60 minutes
Setting Time	Within 24 hours		< 24 hours
Flow	> 17mm		Not less than 17 mm
Film Thickness	<50µm		Not more than 50µm
Water Solubility	1.61%		Not more than 3%
Radiopacity	6 mm Al		Not less than 3 mm Al
Flow, film thickness, water solubility, working time, setting time,	Yes	Yes	Yes

and disintegration meet ISO 6876			
Biocompatibility Assessment according to ISO 10993	Yes	Yes	Yes

	Endoseal K212563 Subject Device	Pulp Canal Sealer K152956 Predicate Device
Product Code	KIF	KIF
Indications for Use	Endoseal is 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.	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.
Device Description	Endoseal is a Zinc Oxide/Eugenol root canal sealant. The product is made up of two separate components, a powder base and a liquid catalyst, to form the final device.	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.
Composition	Powder Zinc oxide, barium sulfate, magnesium stearate, thymol iodide Liquid Eugenol Spearmint Oil	Powder Zinc oxide, silver, thymol iodide Liquid Eugenol Balsam Canada
Form	Powder/Liquid	Powder/Liquid
Chemistry of Setting Reaction	Chelation between zin oxide and eugenol	Chelation between zinc oxide and eugenol
Work Time	25-30 minutes	> 45 minutes
Setting Time	45-60 minutes	< 60 minutes Max
Flow	> 17mm	29mm
Film Thickness	<50µm	22.6 µm
Water Solubility	1.09%	0.09%

Radiopacity	6mm Al	Not less than 3mm Al
Flow, film thickness, water solubility, working time, setting time, and disintegration meet ISO 6876	Yes	Yes
Biocompatibility Assessment according to ISO 10993	Yes	Yes

	Nanoseal S K212563 Subject Device	Roeko Seal Root Canal Sealer K983037 Predicate Device	GuttaSil K190510 Reference Device
Product Code	KIF	KIF	KIF
Indications for Use	Nanoseal S is indicated in patients for permanent obturations of root canal after vital extirpation or after treatment of pulpal gangrene and temporary filling.	The Roeko Seal Root Canal Sealer is indicated in patients for permanent obturations of root canal after vital extirpation or after treatment of pulpal gangrene and temporary filling.	GuttaSil is a material for permanent obturation of root canals after vital extirpation and after treatment of pulpal gangrene and temporary filling of the canal.
Device Description	Nanoseal S is a permanent root canal filling material which is silicone based (polydimethylsiloxane). It is cold flowable and is in a dual barrel cartridge.	Roeko Seal is a permanent root canal filling material, which is silicone based (polydimethylsiloxane) and consists additionally of zircondioxide, paraffin-based oil, silicon oil, hexachloroplatinic acid and silicic acid.	GuttaSil, a product in the form of a paste which combines gutta-percha with a sealer. The gutta-percha powder is mixed in a matrix of polyvinylsiloxane. It is convenient since sealing and obturation are simultaneously possible without heating and the root canal can be filled in a quick manner. This device contains a syringe, auto-mix& Endo tips, spatula, and mixing pads.

Composition	Base Siloxanes, paraffin oil, silanated silica, zirconium oxide, silver, colorant Catalyst Siloxanes, paraffin oil, silanted silica, zirconium oxide, platinum catalyst	Polydimethylpolymethyl hydrogen siloxane, silicone oil, paraffin oil, zirconium oxide, hexchloropatinic acid	Siloxanes, zirconium dioxide, gutta percha, zinc oxide, silver, platinum catalyst, colorant
Form	Two Pastes (Base and Catalyst)	Two Pastes (Base and Catalyst)	
Work Time	8-10 minutes	> 60 minutes	
Setting Time	10-15 minutes	< 24 hours	
Flow	>17mm	>17mm	
Film Thickness	<50µm	<50µm	
Water Solubility	1.06%	< 3.0% by mass	
Radiopacity	6 mm Al	Not less than 3mm Al	
Flow, film thickness, water solubility, working time, setting time, and disintegration meet ISO 6876	Yes	Yes	Yes
Biocompatibility Assessment according to ISO 10993	Yes	Unknown	Yes

	Zical Ultra Paste K212563 Subject Device	Tubli-Seal K153067 Predicate Device	Vitapex K973667 Reference Device
Product Code	KIF	KIF	KIF
Indications for Use	Zical Ultra Paste is used for permanent obturation of the root canal space with the aid of obturating points.	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.	For use to stimulate the healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients. Used to promote healing effects and to help prevent bacterial

			contamination of the canal, as the two ingredients improve the induction effect for hard tissue induction and deposition. To be used as a medicament for the treatment of infected root canals, and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete. For use in the treatment of infected root canals, or following pulpectomy, or for apexegenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha.
Device Description	Zical Ultra Paste is a two-part, base/accelerator, paste/paste system that is mixed in equal portions. The mixture is carried to the root canal with endodontic obturation points. The	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	Vitapex is a pre-mixed calcium hydroxide and iodoform paste which is a temporary or permanent root canal filling material. It comes in a syringe.

	product comes in a dual barrel cartridge.	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.	
Composition	Base Zinc oxide Iodoform Barium sulfate Sodium borate Bismuth subcarbonate Olive oil Catalyst Eugenol Resin Silica Acetic acid	Base Zinc oxide Barium sulfate White mineral oil Catalyst Eugenol White mineral oil 5,5'-diisopropyl-2,2' – dimethyldiphenyl – 4,4'diyl dihypoiodite resin	Calcium hydroxide Iodoform Silicone oil Inert ingredients
Form	Two Pastes (Base and Catalyst)	Two Pastes (Base and Catalyst)	
Work Time	8-10 minutes	>60 minutes	
Setting Time	10-15 minutes	70 minutes	
Flow	> 17mm	29mm	
Film Thickness	<50µm	13.04 µm	
Water Solubility	1.31%	0.70%	
Radiopacity	6 mm Al	5 mm Al	
Flow, film thickness, water solubility, working time, setting time, and disintegration meet ISO 6876	Yes	Yes	Yes
Biocompatibility Assessment according to ISO 10993	Yes	Yes	Unknown

	Zical Ultra Powder/Liquid K212563 Subject Device	Tubli-Seal K153067 Predicate Device	Vitapex K973667 Reference Device
Product Code	KIF	KIF	KIF
Indications for Use	Zical Ultra Powder/Liquid is used	The Tubli-Seal product line (Tubli-Seal/Tubli-Seal	For use to stimulate the

	for permanent obturation of the root canal space with the aid of obturating points.	Xpress/Tubli-Seal EWT/Tubli-Seal EWT Xpress) is used for permanent obturation of the root canal space with the aid of obturating points.	healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients. Used to promote healing effects and to help prevent bacterial contamination of the canal, as the two ingredients improve the induction effect for hard tissue induction and deposition. To be used as a medicament for the treatment of infected root canals, and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete. For use in the treatment of infected root canals, or following pulpectomy, or for apexegenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time

			of final filling with gutta-percha.
Device Description	Zical Ultra Powder/Liquid is a two-part, powder/liquid system for permanent filling of root canals. The mixture is carried to the root canal with endodontic obturation 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.	Vitapex is a pre-mixed calcium hydroxide and iodoform paste which is a temporary or permanent root canal filling material. It comes in a syringe.
Composition	Powder Zinc oxide resin Iodoform Barium sulfate Bismuth subcarbonate Zinc acetate Catalyst Eugenol Olive oil	Base Zinc oxide Barium sulfate White mineral oil Catalyst Eugenol White mineral oil 5,5'-diisopropyl-2,2' – dimethyldiphenyl – 4,4'diyl dihypoiodite resin	Calcium hydroxide Iodoform Silicone oil Inert ingredients
Form	Powder/liquid	Powder/liquid	
Setting Time	45-60 minutes	70 minutes	
Flow	> 17mm	29mm	
Film Thickness	<50µm	13.04µm	
Water Solubility	0.75%	0.70%	
Radiopacity	6 mm Al	5 mm Al	
Flow, film thickness, water solubility, working time, setting time, and disintegration meet ISO 6876	Yes	Yes	Yes
Biocompatibility Assessment according to ISO 10993	Yes	Yes	Unknown

Conclusion: Prevest Denpro Root Canal Sealers are substantially equivalent to the predicate device, Sealapex. They have the same indications, similar testing, and very similar ingredients. The subject devices and predicate or reference devices have similar forms, work, and setting times, flow, film thickness, water solubility, radiopacity. The pass criteria are either the same as the predicate and reference devices (in some cases ISO 6872 sets pass criteria for all root canal sealers) or the pass criteria are tighter than those of the predicate and reference devices. Having a tighter pass criteria would not change the substantial equivalence because the subject devices would also still meet the pass criteria used by the predicate and reference devices.

Any differences in the measured parameters are minor and do not change the substantial equivalence because all the values meet ISO 6876 or other relevant standard. Both the subject devices and the predicate device have physical parameters which meet requirements of the relevant ISO standards. Both the subject devices and predicate/reference devices have biocompatibility assessments according to ISO 10993. Shelf life testing is similar to the shelf life testing of predicate or reference device. Reference devices are included to cover any ingredients, or indications not covered by the predicate devices. Any differences in ingredients are minor and do not change the substantial equivalence.