May 13, 2022

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

Re: K212475
Trade/Device Name: Prevest Denpro Cavity Liners (Apacal ART, Cal LC, Calcigel, CalUltra)
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: Class II
Product Code: EJK
Dated: March 10, 2022
Received: March 15, 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)*
K212475

Device Name
Prevest Denpro Cavity Liners (Apacal ART, Cal LC, Calcigel, CalUltra)

Indications for Use *(Describe)*

Apacal ART and is suitable for several indications including:
- Liner to be applied to the interior of a prepared cavity prior to the insertion of restorative materials.
- Indirect pulp capping or management of deep caries lesions, or
- Direct pulp capping

CAL-LC is indicated for use as a cavity liner and pulp capping material. It is self-adhering and highly filled.

Calcigel is a calcium hydroxide paste that has a creamy consistency and is suitable for several indications including:
- Indirect pulp capping or management of deep caries lesions, or
- Direct pulp capping

CalUltra is a hard-setting calcium hydroxide cavity liner and pulp capping agent to be used in conjunction with all permanent restorative techniques.

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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K212475

Prevest DenPro Cavity Liners (Apacal ART, Cal LC, Calcigel, CalUltra)
510K Summary
May 3, 2022

Name and Address: Prevest Denpro Limited
Export Promotion Industrial Park
Bari Brahmana, Jammu 181133 India
Contact Person: Atul Modi
Email: prevestindia@gmail.com
Telephone: (941) 919 4280

Name of device: Prevest Denpro Cavity Liners (Apacal ART, Cal LC, Calcigel, CalUltra)
Common name: cavity liner
Classification Name: calcium hydroxide cavity liner
CFR: 21 CFR 872.3250
Primary Product Code: EJK

Submission Contact:

Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
(704)450-9934
angela@blackwelldevice.com

Device Description:

Apacal ART is a light cured single-component paste reinforced with tricalcium phosphate and hydroxyapatite. It is sold in a syringe with accompanying applicator tips.

CAL-LC is a highly filled cavity liner and pulp capping material. It is sold in a syringe with accompanying applicator tips.

Calcigel is a creamy, ready -to -use calcium hydroxide paste with a pH above 11. It is sold in a syringe with accompanying applicator tips.

CalUltra is a hard-setting calcium hydroxide cavity liner and pulp capping agent. CalUltra is a two-part base/catalyst paste/paste system. It is sold in a tubes with accompanying spatula and mixing pad.

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Indications for Use:

Device Name	Indications
Apacal ART	Apacal ART and is suitable for several indications including: • Liner to be applied to the interior of a prepared cavity prior to the insertion of restorative materials. • Indirect pulp capping or management of deep caries lesions, or • Direct pulp capping
Cal LC	CAL-LC is indicated for use as a cavity liner and pulp capping material. It is self-adhering and highly filled.
Calcigel	Calcigel is a calcium hydroxide paste that has a creamy consistency and is suitable for several indications including: • Indirect pulp capping or management of deep caries lesions, or • Direct pulp capping
CalUltra	CalUltra is a hard-setting calcium hydroxide cavity liner and pulp capping agent to be used in conjunction with all permanent restorative techniques.

Testing Summary:

Apacal ART, and Cal LC were tested for appearance, flexural strength, depth of cure, water sorption/solubility, and radio-opacity according to protocols based on ISO 9917-2:2017, ISO 4049:2019 and ISO 13116:2014. Calcigel was tested for appearance and flow according to ISO 6876:2012, radio-opacity according to ISO 13116: 2014 and pH according to USP 971. CalUltra was tested for appearance and compressive strength according to ISO 9917-1:2017, water solubility and setting time according to ISO 6876:2012, radio-opacity according to ISO 13116:2014, and pH according to USP 971.

Shelf life testing was completed on all devices using relevant protocols also used for the physical characteristics tested. Shelf life for all four cavity liners is 3 years.

All tests results met the criteria in standards.

The cavity liners contain ingredients found in the predicate and reference devices. They are used for the same type of contact, external communicating with contact to tissue/bone/dentin. The indications for

use of the devices and the predicate devices are the same so the risks incurred for use of the ingredients are the same. Since no new risks are introduced, no biocompatibility testing was done.

Mechanism of Action: Apacal ART and Cal LC are light cured. Calcigel remains a paste with another cured material being placed on top of it to seal it. CalUltra cures via a base catalyst reaction.

Predicate Device: CleaniCal K201799

Additional Predicate Devices: Ultra Blend Plus K970113, Life Regular Set/ Life Fast Set K150559

Reference Devices: Cavios Calcium Hydroxide Cavity Liner K111668 (for ingredients),), RMGI Low Viscosity K123265 (for ingredients), DIAPASTE K190091 (for ingredients), Adseal K042769 (for ingredients), VLC Dycal II K922721 (for ingredients)

Substantial Equivalence:

The cavity liners have similar ingredients to the predicate and reference devices, the same indications for use, and similar physical parameter testing.

Cavity Liners from Prevest Denpro

Name	ApaCal ART (subject device)	CleaniCal (predicate device)	Cavios Calcium Hydroxide Cavity Liner (reference device for ingredients)
510k Number	K212475	K201799	K111668
Common Name	Cavity Liner	Calcium Hydroxide Paste	Cavity Liner
Classification Name	Calcium Hydroxide Cavity Liner	Calcium Hydroxide Cavity Liner	Calcium Hydroxide Cavity Liner
Class	II	II	II
Product Code	EJK	EJK, KIF	EJK
CFR	872.3250	872.3250	872.3820
Indications for Use	Apacal ART and is suitable for several indications including: • Liner to be applied to the interior of a prepared cavity prior to the insertion of restorative materials. • Indirect pulp capping or management of deep caries lesions, or	Cleanical is a calcium hydroxide paste that has a creamy consistency and is suitable for several indications including: • Temporary disinfectant dressings in the obturation of root canals • Indirect pulp capping or management of deep caries lesions, or	Cavios cavity Liner is to be applied to the interior of a prepared cavity prior to the insertion of restorative materials. Cavios Cavity Liner is indicated for use in the general dental population.

	• Direct pulp capping	• Direct pulp capping	
Device Description	Apacal ART is a light cured single-component paste reinforced with tricalcium phosphate and hydroxyapatite.	Cleanical is a pre-filled syringe of calcium hydroxide paste with a pH of 12.3.	Cavios is a light cured single-component yellow-white paste for use as a dentin liner and paste.
Formula	urethane dimethyacrylate, triethylene glycol dimethacrylate, barium sulfate, silanated barium glass powder, amorphous fumed silica, tricalcium phosphate, hydroxyapatite, calcium hydroxide, photo initiators, and stablizers	Calcium hydroxide Zirconium dioxide Excipients (n-Methyl-2-pyrrolidone, Hypromellose)	Urethane dimethacrylate, Tricalcium phosphate Barium sulfate, photo initiator
Mechanism of Action	Light Cure	Unknown	Light Cure
Light Cure Time	30-40 sec	Unknown	20 sec
Water Sorption	13.6 µg/mm^3	Unknown	33 µg/mm^3
Water Solubility	4.5 µg/mm^3	Unknown	0.8 µg/mm^3
Flexural Strength	99.1 MPa	Unknown	59.9 MPa
Package	Pre-filled syringe	Pre-filled syringe	Pre-filled syringe
Sterility	Non-sterile	Non-sterile	Non-sterile
Shelf Life	3 years	2 years	3 years

Name	CAL-LC (subject device)	Ultra Blend Plus (additional predicate device)	RMGI Low Viscosity (reference device for ingredients)
510k Number	K212475	K970113	K123265
Common Name	Cavity liner and/or base material	Cavity liner and/or base material	Dental cement, cavity liner
Classification Name	Calcium hydroxide cavity liner	Calcium hydroxide cavity liner	Dental cement, cavity liner
Class	II	II	II
Product Code	EJK	EJK	EMA, EJK
CFR	872.3250	872.3250	872.3275
Indications for Use	CAL-LC is indicated for use as a cavity liner and pulp capping material.	Ultra Blend Plus is indicated for use as a cavity liner and pulp capping material. It is	Pulpdent RMGI Low Viscosity is a resin-modified glass ionomer preparation used by

	It is self-adhering and highly filled.	self-adhering and highly filled.	dental professionals as a liner, base, or luting material in dental restorations.
Device Description	CAL-LC is a highly filled cavity liner and pulp capping material.	Ultra Blend Plus is a highly filled cavity liner and pulp capping material.	Pulpdent RGMI Low Viscosity is a resin-modified glass ionomer in two pastes.
Formula	diurethane dimethyacrylate, Barium sulfate, calcium hydroxide, Silanated barium glass powder, Amorphous fumed silica, Photo initiators, and stablizers	Diurethane dimethacrylate, barium sulfate, calcium hydroxide, calcium hydroxyapatite, triethylene glycol dimethacrylate, amine methacrylate	Part A: Diurethane dimethacrylate, polyacrylic acid/maleic acid copolymer, water, barium borosilicate glass, silica, reducing agents, photo initiators Part B: Diurethane dimethacrylate, aluminofluorosilicate ionomer glass, silica, oxidizing agents
Mechanism of Action	Light Cure	Light Cure	Light Cure
Flexural Strength	96.3 MPa	Unknown	88 MPa
Light Cure Time	30-40 sec	10 sec	20 sec
Package	Pre-filled syringe	Pre-filled syringe	Auto-mix syringe
Sterility	Non-sterile	Non-sterile	Non-sterile
Shelf Life	3 years	Unknown	Unknown

Name	Calcigel (subject device)	CleaniCal (predicate device)	DIAPASTE (reference device for ingredients)
510k Number	K212475	K201799	K190091
Common Name	Calcium Hydroxide Paste	Calcium Hydroxide Paste	Root Canal Filling Resin
Classification Name	Calcium Hydroxide Cavity Liner	Calcium Hydroxide Cavity Liner	Root Canal Filling Resin
Class	II	II	II
Product Code	EJK	EJK, KIF	KIF
CFR	872.3250	872.3250	872.3820
Indications for Use	Calcigel is a calcium hydroxide paste that has a creamy consistency and is suitable for several indications including:	Cleanical is a calcium hydroxide paste that has a creamy consistency and is suitable for several indications including:	Aqueous ointment material that temporarily fills the root canal for the following indications: • Apexification

	• Indirect pulp capping or management of deep caries lesions, or • Direct pulp capping	• Temporary disinfectant dressings in the obturation of root canals • Indirect pulp capping or management of deep caries lesions, or • Direct pulp capping	• Temporary root filling • Root canal filling for primary teeth • Vital pulpotomy • Temporary pulp capping
Device Description	Calcigel is a creamy, ready -to -use calcium hydroxide paste with a pH above 11.	Cleanical is a pre-filled syringe of calcium hydroxide paste with a pH of 12.3.	Diapaste is a calcium hydroxide paste with barium sulfate, used as a temporary root canal filling material.
Formula	Calcium hydroxide Demineralized water Barium sulfate Polyethylene glycol 400 Hydroxypropyl methoxycellulose	Calcium hydroxide Zirconium dioxide Excipients (n-Methyl-2-pyrrolidone, Hypromellose)	Calcium hydroxide Water Calcium carbonate Zinc oxide Barium Sulfate Polyethylene glycol 400 Polysorbate (Tween 80)
Calcium Hydroxide %	30%	30%	22-26%
Mechanism of Action	Paste to be sealed over with a cured cavity liner.	Paste to be sealed over with a cured cavity liner.	Paste to be sealed over with a cured cavity liner.
pH	11-13	12.3	12.5
Package	Pre-filled syringe	Pre-filled syringe	Pre-filled syringe
Sterility	Non-sterile	Non-sterile	Non-sterile
Shelf Life	3 years	2 years	3 years

Name	CalUltra (subject device)	Life Regular Set/ Life Fast Set (Additional predicate device))	Adseal (reference device for ingredients)	VLC Dycal II (reference device for ingredients)
510k Number	K212475	K150559	K042769	K922721
Common Name	Cavity liner and/or base material	Cavity liner and/or base material	Root canal sealer	Cavity liner
Classification Name	Calcium hydroxide cavity liner	Calcium hydroxide cavity liner	Root canal filling resin	Calcium hydroxide cavity liner
Class	II	II	II	II
Product Code	EJK	EJK	KIF	EJK

CFR	872.3250	872.3250	872.3820	872.3250
Indications for Use	CalUltra is a hard-setting calcium hydroxide cavity liner and pulp capping agent to be used in conjunction with all permanent restorative techniques.	Life is a hard-setting calcium hydroxide cavity liner and pulp capping agent to be used in conjunction with all permanent restorative techniques.	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. Application to exposed, vital pulp tissue (direct pulp capping). 2. Application to dentin as a protective barrier between restorative materials and deep vital dentin (indirect pulp capping) or where dentin to restorative material contact is not desired.
Device Description	CalUltra is a hard-setting calcium hydroxide cavity liner and pulp capping agent. CalUltra is a two-part base/catalyst paste/paste system.	Life is a hard-setting calcium hydroxide cavity liner and pulp capping agent. Life is a two-part base/catalyst paste/paste system.	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 two components, the	Dycal® Calcium Hydroxide Liner is a two-component, rigid-setting, self-curing material designed for use in direct and indirect pulp capping and as a protective liner under dental adhesives, varnishes, filling materials, cements, and other base materials. It will not inhibit the polymerization of acrylic and composite restorations.

			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 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, with the chambers of a two component plastic syringe, packaged with a disposable applicator.	
Formula	Base: Calcium hydroxide, Ethylene toluene sulfonamide, Zinc oxide, Zinc stearate Catalyst: Ethylene glycol salicylate, Tricalcium phosphate,	Base: Calcium dihydroxide, Zinc oxide, calcium oxide, ethylene toluene sulfonamide Catalyst: Methyl salicylate, 2,2 dimethylpropane – 1,3 diol, Fumed silica	Paste A: Ethylene glycol salicylate Bismuth subcarbonate Epoxy oligomer resin Paste B: Polybutanediol aminobenzoate, Calcium phosphate Bismuth subcarbonate	Base: disalicylate ester of 1,3 butylene glycol, calcium phosphate, calcium tungstate, zinc oxide, iron oxide Catalyst: calcium hydroxide, ethyl toluenesulfonamide, zinc stearate, titanium dioxide,

	Zinc oxide, Barium sulfate, zinc stearate, fumed silica, pigments			zinc oxide, iron oxide
Mechanism of Action	Set by base/catalyst reaction	Set by base/catalyst reaction	Set by base/catalyst reaction	Set by base/catalyst reaction
Setting Time	1-3 minutes	Unknown	70 minutes	2-3 minutes
Water solubility	3.8%	Unknown	0.24%	Unknown
pH	9.2	Unknown	9.06	Unknown
Package	Tubes	Tubes	dual syringe	Tubes
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Shelf Life	3 years	Unknown	Unknown	Unknown

Conclusion: Prevest Denpro Cavity Liners are substantially equivalent to the predicate device, Cleanical. They have the same indications, same mechanism of action, similar testing, and very similar ingredients. Both the subject devices and the predicate device have physical parameters which meet requirements of the relevant ISO standards. Shelf life testing is similar to the shelf life testing of predicate or reference device including Cavios K111668 which also has a 3 year shelf life. 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.