August 25, 2026

Guilin Kevin Peter Technology Co., Ltd.
Libin Zhang
Regulatory Affairs Manager
North Side Of Linsu Rd., Lingui Town, Lingui Dist.
Guilin, Guangxi 541100
CHINA

Re: K261514
Trade/Device Name: Calcium Hydroxide Temporary Filling Material (KP-Cal)
Regulation Number: 21 CFR 872.3820
Regulation Name: Root canal filling resin
Regulatory Class: Class II
Product Code: KIF, EJK
Dated: July 21, 2026
Received: July 21, 2026

Dear Libin Zhang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
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Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261415

Please provide the device trade name(s).

Calcium Hydroxide Temporary Filling Material (KP-Cal)

Please provide your Indications for Use below.

Calcium Hydroxide Temporary Filling Material is suitable for several indications including：
-Temporary root canal filling;
-Vital pulpotomy
-Temporary pulp capping.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary-K261514

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

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Date of Preparation: August 19, 2026

2.0 Device Information

Trade/Device Name: Calcium Hydroxide Temporary Filling Material
Common Name: Resin, root canal filling
Model: KP-Cal
Panel: Dental
Regulation Number: 21 CFR 872.3820
Device Class: Class II
Product Code: KIF

3.0 Identification of Predicate Device

Primary Predicate Device

510(k) Number: K210904
Device Name: Metapaste Plus
Common Name: Root Canal Filling Resin
Panel: Dental
Regulation Number: 21 CFR 872.3820
Device Class: Class II
Product Code: KIF
Manufacturer: Meta Biomed Co.,Ltd

Reference Predicate Device:

510(k) Number:	K060365
Device Name:	Calcium hydroxide paste
Common Name:	Calcium hydroxide cavity liner
Model:	ApexCal
Panel:	Dental
Regulation Number:	21 CFR 872.3250
Device Class:	Class II
Product Code：	EJK
Manufacturer:	Ivoclar Vivadent,Incorporated

4.0 Indication for Use Statement

Calcium Hydroxide Temporary Filling Material is suitable for several indications including：

-Temporary root canal filling;

-Vital pulpotomy

-Temporary pulp capping.

5.0 Device Description

Calcium Hydroxide Temporary Filling Material is a premixed, immediately applicable, hydrophilic root canal temporary dressings. KP Cal does not solidify in the root canal and is easy to thoroughly flush out after treatment.

6.0 Summary of Non-Clinical Testing

The following testing was conducted on subject device:

- Performance testing of Appearance, pH range, Calcium hydroxide content, Loading volume according to manufacturer standard.

  Performance testing of Flowability, Radio-opacity, Film thickness according to ISO 6876.
- Biocompatibility tests were performed according to ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10, ISO 10993-11, ISO 10993-23.
- Shelf life test:Appearance, pH range, Calcium hydroxide content, Loading volume(manufacturer standard), Flowability, Radio-opacity, Film thickness(ISO 6876).

7.0 Summary of Clinical Testing

Clinical testing was not required for this submission.

8.0 Technological Characteristics and Substantial Equivalence

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 1 General Device Characteristics Comparison Table

Item	Subject device	Primary predicate device	Secondary predicate device K060365	Discuss/Justify the difference
Product Name	KP-Cal Calcium Hydroxide Temporary Filling Material	Metapaste Plus Calcium Hydroxide Temporary Filling Material	ApexCal Calcium hydroxide paste	--
Product Code	KIF	KIF	EJK	--
Regulation No.	21 CFR 872.3820	21 CFR 872.3820	21 CFR 872.3250	--
Class	II	II	II	--
Device description	Calcium Hydroxide Temporary Filling Material is a premixed, immediately applicable, hydrophilic root canal temporary dressings. KP Cal does not solidify in the root canal and is easy to thoroughly flush out after treatment.	Metapaste Plus is a water-based calcium hydroxide paste material for root canal temporary filling. It is pre-mixed in a syringe for convenient delivery in the root canal. When applied to root canal, it is alkaline by calcium hydroxide. The state of the treatment can be confirmed by the radiopacity of barium sulfate contained. Also, it is water-soluble and easy to remove.	ApexCal is a creamy radiopaque,ready-to-use calcium hydroxide paste with a pH above 12.5.	Equivalent* (Analysis 1)
Indication for use	Calcium Hydroxide Temporary Filling Material is suitable for several indications including： -Temporary root canal filling; -Vital pulpotomy -Temporary pulp capping.	Metapaste plus is a biocompatible root canal filling used for the temporary filling of root canals after endodontic surgery. Metapaste Plus can be used on its own and for vital pulpectomy in decidious teeth.Metapaste Plus is intended for use by qualified healthcare personnel trained in its use.	ApexCAL 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;	Equivalent* (Analysis 2)

			-Indirect pulp capping or management of deep caries lesions; or -Direct pulp capping.	
Prescription Use	Yes	Yes	Yes	Equivalent
Composition of Materials	This product consists of calcium hydroxide, zirconium dioxide, propylene glycol, polyethylene glycol.	Calcium hydroxide, Barium sulfate, Aluminum oxide, Titanium oxide, Polyethylene glycol, Dihydrogen oxide	ApexCal contains calcium hydroxide and bismuth carbonate in a mixture of water, glycerine, polyethylene glycol and other supplementary agents.	Similar (Analysis 3)
Liquid Formula	Paste	Paste	Paste	Equivalent
Packaging	Pre-loaded syringe	Pre-loaded syringe	Pre-loaded syringe	Equivalent
Sterile	Non-sterile	Non-sterile	Non-sterile	Equivalent
Shelf Life	2 years	2 years	2 years	Equivalent
Physical Properties	The subject device and the predicate device have substantially equivalent physical properties including flowability,Radio-opacity,Film thickness,pH range,Calcium hydroxide content according to ISO 6876 and manufacturer standard.			Similar (Analysis 4)
pH range	12.32	12.40	12.46	
Calcium hydroxide concentration	26%	25%	24%	
Flowability	19.9	20.8	20.4	
Radiopacity	4.5	4.5	4.6	
Film thickness	19	18	22	
Biocompatibility	Conformed to ISO 10993 and ISO 7405.	Conformed to ISO 10993 and ISO 7405.	Conformed to ISO 10993 and ISO 7405.	Equivalent

Analysis:

1) It’s simply a difference in terminology.The subject device and predicate device are all pre-mixed,ready-to-use,strongly alkaline calcium hydroxide paste.
2) KP-Cal and the Primary predicate device(Metapaste plus) can be used for temporary root canal filling and pulpotomy. The indication for temporary pulp capping is only found in the KP-Cal's indication for use and not in the Metapaste Plus's. This technique is commonly used for temporary root canal fillings ,and ,as such, does not affect the equivalence of the indications of the subject and predicate devices.
3) The main component is same,but some other components are different. The main difference is in the composition of the retardant and solvent, but it does not affect the clinical performance and safety of the product.The biocompatibility and the performance test results supported the equivalence,the subject device is substantially equivalent to the predicate device.
4) Performance comparison testing was conducted to the predicate device and current subject device to compare their performance according to ISO 6876 and manufacturer standard.The performance technological parameters are little different with those of the predicate,and all meet the requirement. So the difference will not cause the difference in safety or efficacy.

Therefore, it is concluded that the subject device is substantially equivalent to the predicate device.

9.0 Conclusion

KP-Cal Calcium Hydroxide Temporary Filling Material has the similar intended use as the predicate devices.It has similar physical and biocompatible properties and demonstrates comparable performance specifications to the predicate devices.

The chemical compositions might slightly different from the predicate devices, both are used calcium hydroxide main composition as medicament,and additional component is used to make its appropriate workability.

The bench and biocompatibility testing performed demonstrates that any differences in their technological characteristics do not raise any new questions as to safety and effectiveness.Therefore, it is concluded that KP-Cal is substantially equivalent to the predicate devices.Hence,its equivalent is acceptable because it shows no clinically significant difference in the performance and safety to the device.