June 29, 2026

Guilin Kevin Peter Technology Co., Ltd.
℅ Boyle Wang
General Manager
ABMED Medical Technology PTY, Ltd.
48/6 Herbert St.
St Leonards, NSW 2065
Australia

Re: K261415
Trade/Device Name: Injectable Root Canal Sealer (KP-Root SP)
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: April 30, 2026
Received: April 30, 2026

Dear Boyle Wang:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
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

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).

Injectable Root Canal Sealer (KP-Root SP)

Please provide your Indications for Use below.

- 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.

KP-Root SP is suitable for use in the single cone and lateral condensation technique.

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

K261415

This summary of 510(k) substantial equivalence is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

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Designated Submission Correspondent

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Address: 48/6 Herbert Street, St Leonards NSW 2065, Australia
Telephone: + 61 432 758 222
Email: info@abmed.com.au

Date of Preparation: June 27, 2026

2.0 Device Information

Trade Name: KP-Root SP
Device Name: Injectable Root Canal Sealer
Common Name: Root Canal Sealer
Classification Name: Resin, Root Canal Filling
Model: KP-Root SP

3.0 Classification

Production code: KIF
Regulation number: 21 CFR 872.3820
Classification: Class II
Panel: Dental

4.0 Identification of Predicate Device and Reference Device

Predicate Device:

510(k) Number: K080917
Product Name: iRoot SP
Manufacturer: Innovative BioCeramix, Inc.

This predicate device has not been subject to a design-related recall.

5.0 Indication for Use Statement

● 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.

KP-Root SP is suitable for use in the single cone and lateral condensation technique.

6.0 Device Description

KP-Root SP is a premixed ready-to-use, injectable bioceramic paste, which is used for tight sealing and permanent filling of root canal. KP-Root SP is a radiopaque material, which requires the presence of water to set and harden. KP-Root SP is packaged in a preloaded syringe and is very convenient to use.
KP-Root SP is available in two preloaded syringe mode that provide different in specification in 0.5g,1g, 2g,3g; The only difference between the types is the net weight.

7.0 Summary of Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the Technical Requirements of Injectable Root Canal Sealer issued by Guilin Kevin Peter Technology Co., Ltd. and the standards ISO 6876:2012 Dentistry - Root canal sealing materials, including:
- Composition and appearance
- Packing volume
- Flow
- Setting time
- Film thickness
- Solubility and disintegration
- Dimensional change after setting
- Radiopacity
- pH value

All test results demonstrated that the subject device meets the requirements of ISO 6876 and the product technical specifications.

Biocompatibility testing

- Ames Test - ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- In vitro mammalian chromosomal aberration test - ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- In Vitro Cytotoxicity Test - ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Sensitization - ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- Acute systemic Toxicity Test - ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Pyrogenicity Test- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Subchronic systemic Toxicity Test - ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Implantation effects - ISO 10993-6:2016 Biological evaluation of the medical devices – Part 6: Tests for Local Effects after Implantation.

8.0 Summary of Clinical Testing

Clinical testing was not required for this submission.

9.0 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 K261415	Predicate device K080917	Remark
Product Name	KP-Root SP	iRoot SP	--
Product Code	KIF	KIF	Same
Regulation No.	21 CFR 872.3820	21 CFR 872.3820	Same
Class	II	II	Same
Intended Use	● 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. KP-Root SP is suitable for use in the single cone and lateral condensation technique.	* 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. iRoot SP is suitable for use in the single cone and lateral condensation technique.	Same
Prescription Use	Yes	Yes	Same
Basic Chemical Composition	Zirconium oxide, Strontium doped calcium silicates, calcium hydroxide, calcium phosphate monobasic and Filler agents.	Zirconium Oxide, Calcium Silicates, Calcium Hydroxide, Calcium Phosphate Monobasic and Filler Agents	Analysis 1
Performance Standard Conformance	Conformed to ISO 6876 and Technical Requirements of Injectable Root Canal Sealer	Conformed to ISO 6876	Same
Flow	Average Min.value. 26.66	Average Min.value 26.89	Analysis 2
Setting time	9h	10.5h	Analysis 2
Dimensional change following setting	0.04 in shrinkage	0.06 in shrinkage	Analysis 2
Film thickness	Average 21.3	Average 19.3	Analysis 2
Solubility and disintegration	Solubility: Average 0.67% Disintegration: Compliance requirement	Solubility: Average 0.93% Disintegration: Compliance requirement	

Radio-opacity	Compliance requirement. Equivalent to the thickness of 6 mm aluminum plate	Compliance requirement. Equivalent to the thickness of 6 mm aluminum plate (maybe affected by bubbles)	Analysis 2
pH	Average12.66	Average 12.62	
Microbial Limit	Aerobic Plate Count: ＜ 10 cfu/g Yeast and Mold: ＜10 cfu/g Escherichia ciol:ND Staphylococcus aureus:ND Pseudomonas Aeruginosa:ND	Aerobic Plate Count: ＜10 cfu/g Yeast and Mold: ＜10 cfu/g Escherichia ciol:ND Staphylococcus aureus:ND Pseudomonas Aeruginosa:ND	
Acid Soluble Arsenic Content	Acid soluble arsenic ＜ 2mg/kg Acid ＜100mg/kg	Acid soluble arsenic ＜ 2mg/kg Acid ＜100mg/kg	
Flexural strength	(6.24 ± 0.13) MPa	(6.46 ± 0.13) MPa	
Compressive strength	(49.8 ± 0.6)MPa	(49.2 ± 1.3) MPa	
Root Canal Sealing Ability	There was no significant difference in root canal sealing between the subject device and the predicate device.		
Treatment Site	Root canal following vital pulp-extirpation	Root canal following vital pulp-extirpation	Same
Sterile	Non-sterile	Non-sterile	Same
Biocompatibility	Comply with ISO 10993-1:2018, FDA Guidance, tests included cytotoxicity, sensitization, pyrogenicity, acute systemic toxicity, subchronic systemic toxicity test, implantation effect , Ames test and In vitro mammalian chromosomal aberration test.	Comply with ISO 10993-1, FDA Guidance	Same
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Same

Analysis 1:

iRoot SP Root Canal Sealer was identified as the predicate device due to the subject device having similar materials and delivery form (i.e. premixed ready-to-use injectable paste) to the predicate. Analysis and Research Report on the chemical

composition of the predicate device iRoot SP Root Canal Sealer to provide reference for the formulation design of KP-Root SP.

Also, the biocompatibility testing completed in alignment ISO 10993-1 and ISO 7405:2018 respectively demonstrate that any material differences between the subject device and predicate device do not raise any new questions as to safety and effectiveness.

Analysis 2:
The performance technological parameters are little different with those of the predicate. Performance comparison testing was conducted to the predicate device and current subject device to compare their performance according to the Technical Requirements of “Injectable Root Canal Sealer”, which is identical to ISO 6876:2012, and the comparison testing results shown both the subject device and the predicate device are all complied with Technical Requirements of “Injectable Root Canal Sealer” issued by Guilin Kevin Peter Technology Co., Ltd.

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

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the differences between the proposed device and the predicated device are insignificant in terms of substantial equivalence. The subject device is substantially equivalent to the predicate device in K080917.