



January 12, 2026

Medicus Co., Ltd.
Da Hyeon Ku
RA Associate
#1210, 134, Gongdan-Ro, Heungdeok-Gu
Cheongju-Si, 28576
Republic Of Korea

Re: K253167
Trade/Device Name: Any-Paste
Regulation Number: 21 CFR 872.3820
Regulation Name: Root canal filling resin
Regulatory Class: Class II
Product Code: KIF
Dated: September 26, 2025
Received: September 26, 2025

Dear Da Hyeon Ku:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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 -
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For Michael E Adjodha, MChE, 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.

K253167

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Please provide the device trade name(s).

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Any-Paste

Please provide your Indications for Use below.

?

- Any-Paste is a biocompatible root canal filling used for the temporary filling of root canals after endodontic surgery
- Any-Paste can be used on its own and for vital pulpotomy in deciduous teeth
- Any-Paste is intended for use by qualified healthcare personnel trained in its use

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

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

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510(k) Summary K253167

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Dec 22, 2025

1. Submitter/Contact Person

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3. Device

- Trade Name: Any-Paste
- Common Name: Temporary Root Canal Filling Material
- Classification Name: Resin, Root Canal Filling
- Product Code: KIF
- Classification regulation: 21 CFR 872.3820

4. Predicate Device:

Metapaste Plus by META BIOMED CO., LTD. (K210904)

5. Description:

Any-Paste is an effective intracanal medicament and temporary root canal filling material for pulp capping and treatment of infected root canals. The material, primarily composed of barium sulfate and calcium hydroxide and radiopacity. As a water-soluble formulation, it can be easily

cleaned and removed. Provided in a pre-mixed paste form in a convenient syringe, the material remains stable within the syringe without separation or hardening.

6. Indication for use:

- Any-Paste is a biocompatible root canal filling used for the temporary filling of root canals after endodontic surgery
- Any-Paste can be used on its own and for vital pulpotomy in deciduous teeth
- Any-Paste is intended for use by qualified healthcare personnel trained in its use

7. Basis for Substantial Equivalence

7.1. Comparison Chart

	Subject Device	Predicate Device	Equivalence evaluation
Manufacturer	MEDICLUS Co., Ltd.	META BIOMED	-
Product Name	Any-Paste 	Metapaste Plus 	-
510k#	-	K210904	-
Product Code	KIF	KIF	
Material	Calcium hydroxide Barium sulfate Polyethylene glycol 400 Aluminium oxide Titanium oxide	Calcium hydroxide Barium sulfate Aluminum oxide Titanium oxide Polyethylene glycol Dihydrogen oxide	Similar
Indications for Use Statement	- Any-Paste is a biocompatible root canal filling used for the temporary filling of root canals after endodontic surgery - Any-Paste can be used on its own and for vital pulpotomy in deciduous teeth - Any-Paste is intended for use by qualified healthcare personnel trained in its use	- 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 pulpotomy in deciduous teeth - Metapaste Plus is intended for use by qualified healthcare personnel trained in its use	Same
Intended User	Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Same
Technological Standard	ISO 6876	ISO 6876	Similar

Characteristics	Flow	22 mm	21 mm	
	Film thickness	15.3 μ m	$\leq 21 \mu$ m	
	Radio-opacity	3.5 mm	3.1 mm	
	pH	11 <	11 <	
Biocompatibility		Biocompatible	Biocompatible	Same
Delivery method		<ul style="list-style-type: none"> • Delivery System: Syringe • Weight: 2g • Disposable tip 	<ul style="list-style-type: none"> • Delivery System: Syringe • Weight: 2g • Disposable tip 	Similar
Period of Use		Prolonged exposure(B) (exceed 24 hours but not 30 days)	Prolonged exposure(B) (exceed 24 hours but not 30 days)	Same
Shelf-Life		3 years	2 years	Same

7.2. Comparison Chart

The subject device has the same indications for use and the technological characteristics as the predicate device. The minor raw materials are different between the devices but the performance and the biocompatibility test results show that it does not raise a concern in safety and effectiveness.

8. Non-Clinical Testing

- Performance Tests including
 - Appearance, Weight, Packaging, Flow, Film thickness, Radio-opacity, pH in accordance with ISO 6876.
- Biocompatibility Tests
 - ISO 10993-1 Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process
 - ISO 10993-5:2009, test for in vitro cytotoxicity
 - ISO 10993-11:2017, Tests for systemic toxicity
 - ISO 10993-10:2021, Tests for skin sensitization

9. Conclusion

The subject device and the predicate device have the same intended use and have the same technological characteristics. Based on the similarities and the test results, we conclude that the subject device is substantially equivalent to the predicate device.