September 19, 2025

Vericom Co., Ltd.
Yunki Kim
Official Correspondent
48,Toegyegongdan 1-Gil
Chuncheon-Si, Gangwon-Do 24427
SOUTH KOREA

Re: K252285
Trade/Device Name: Well-Root PT
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: July 21, 2025
Received: July 23, 2025

Dear Yunki Kim:

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252285

Device Name

Well-Root PT

Indications for Use *(Describe)*

- Pulp Capping
- Repair of Root Perforation
- Repair of Root Resorption
- Root-end Filling
- Apexification

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K252285

Date: July 17, 2025

1. 510K Applicant / Submitter:

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2. Submission Contact Person

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3. Device

- Proprietary Name: Well-Root PT
- Common Name: Root Canal Filling Material
- Classification: Root Canal Filling Material, Class II (21 CFR 872.3820)
- Product Code: KIF
- Review Panel: Dental

4. Predicate Device

ProRoot MTA (K142178) by Dentsply International Inc.
iRoot BP Plus (K092715) by Innovative BioCeramix Inc.

5. Description:

Well-Root PT is ready-to use, premixed, bioceramic paste developed for pulp capping, permanent root canal repair and filling. Well-Root PT is delivered by the capsule containing the mixture of calcium silicate cement, liquid and several compound particles. It sets in the root without the mixing process with additional water. We offer the following five package configurations.

Package Type Name	Package Contents	Capsule Type
Well-Root PT	0.25g capsule 10ea	Capsule Type 1 (Grey & Brown)
Well-Root PT Type A	0.25g capsule 1ea	

Well-Root PT Type B	0.25g capsule 1ea	Capsule Type 2 (Green & Black)
Well-Root PT Type C	0.25g capsule 10ea	
Well-Root PT Evo	0.25g capsule 5ea	

6. Indications for Use

- Pulp Capping
- Repair of Root Perforation
- Repair of Root Resorption
- Root-end Filling
- Apexification

7. Substantial Equivalence Discussion:

Well-Root PT has the same intended use and the principle of operation and also has similar physical and biocompatible properties demonstrating comparable performance specifications to the predicate devices: ProRoot MTA White/Grey (K142178) by Dentsply International, and iRoot BP Plus (K092715) by Innovative BioCeramix.

The difference between Well-Root PT and the primary predicate device (ProRoot MTA) are delivery form and setting time. However, the differences do not affect the safety and effectiveness of product considerably. Delivery forms are just one of the attributes medical devices have for convenience of use. The setting time of the subject device is different from the predicate device, but its test result satisfies the requirement of the standard (ISO 6876) and does not raise an issue of safety and/or performance.

We identified the reference predicate device (iRoot BP Plus) for similar delivery form.

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 Well-Root PT is substantially equivalent to the predicate devices.

	Subject Device	**Primary Predicate Device**	**Reference Predicate Device**
Trade Name	Well-Root PT	ProRoot MTA	iRoot BP Plus
Manufacturer	Vericom Co., Ltd.	Dentsply International Inc.	Innovative BioCeramix Inc.
510K Number	-	K142178	K092715
Product Code	KIF	KIF	KIF

Indications for Use	• Pulp Capping • Repair of Root Perforation • Repair of Root Resorption • Root-end Filling • Apexification	• A root end filling material • For the repair of root canals as an apical plug during apexification • For repair of root perforations during root canal therapy or as a consequence of internal resorption • As a pulp capping material • Pulpotomy of primary teeth in the child (ages>2-12 years) and adolescent (ages>12-21 years) pediatric patient populations	• Repair of Root Perforation • Repair of Root Resorption • Root end Filling • Apexification • Pulp capping
Raw materials	- Calcium silicate compound - Zirconium oxide - Calcium sulfate dehydrate - Calcium sodium phosphosilicate - Polyethylene glycol - Polypropylene glycol	- Bismuth oxide - Tricalcium silicate - Dicalcium silicate - Calcium dialuminate - Calcium sulfate dehydrated	- Tricalcium silicate - Dicalcium silicate - Zirconium oxide - Tantalum pentoxide - calcium sulfate
Principle of operation	Well-Root PT is ready-to use, premixed, bioceramic paste developed for pulp capping, permanent root canal repair and filling. Well-Root PT is delivered by the capsule containing the mixture of calcium silicate cement, liquid and several compound particles. It sets in the root without the mixing process with additional water.	ProRoot MTA White/Gray is a powder consisting of fine hydrophilic particles that set in the presence of moisture. Hydration of the powder creates a colloidal gel that solidifies to form a strong impermeable barrier that fully cures over a four-week period.	iRoot BP Plus Root Repair Material (iRoot BP Plus) is a ready-to-use premixed bioceramic paste developed for permanent root canal repair and surgical applications. iRoot BP Plus is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition. It sets in the root without the mixing process with additional water as it absorbs the moisture from the root.
Performance Standard Conformance	Conformed to ISO 6876	Conformed to ISO 6876	Conformed to ISO 6876
Biocompatibility	Yes	Yes	Yes
Use	Prescription / Hospital	Prescription / Hospital	Prescription / Hospital
Setting time	25 minutes at 37℃	4~6 hours at 37℃	2 hours at 37℃
Delivery Forms	Single paste	Manual mixing of Powder and liquid	Single paste
Sterility	Non-sterile	Non-sterile	Non-sterile
Utility	Single Use	Single Use	Single Use

8. Performance Tests (Non-clinical)

- Performance Tests in accordance with ISO 6876

No.	Test	Standard
1	Radio-opacity	ISO 6876
2	Film Thickness	ISO 6876
3	Solubility and Disintegration	ISO 6876
4	Setting Time	ISO 6876

- Shelf-Life Tests in accordance with ISO 6876

No.	Test	Standard
1	Package	-
2	Appearance	-
3	Setting Time	ISO 6876
4	Film Thickness	ISO 6876

- Biocompatibility Tests in accordance with ISO 10993

No.	Test	Standard
1	Cytotoxicity	ISO10993-5
2	Sensitization	ISO10993-10
3	Oral mucosa irritation	ISO10993-10
4	Acute systemic toxicity	ISO10993-11
5	Bacterial reverse mutation (Ames test)	ISO10993-3
6	Implantation	ISO 10993-6

The test results of non-clinical tests performed on the subject device supported that it is substantially equivalent to the predicate devices despite the differences.

9. Conclusions:

Based on the information provided in this premarket notification, Vericom Co., Ltd. concludes that the Well-Root PT is substantially equivalent to the predicate device as described herein in.