



January 26, 2024

Medicus Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, California 92612

Re: K232182
Trade/Device Name: One-Fil
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: November 28, 2023
Received: November 28, 2023

Dear Priscilla Chung:

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.

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,
Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K232182

Device Name

One-Fil

Indications for Use (Describe)

Permanent sealing of root canal

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.

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K232182

510(k) Summary

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

Date: ___ July 23, 2023 ___

1. Applicant / Submitter:

MEDICLUS CO., LTD.
No. 1210, 134 Gongdan-ro, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, Republic of Korea
Tel : +82-43-211-2877
Fax : +82-43-211-2866

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine CA 92620
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	One-Fil
Common Name:	Dental root canal sealer
Classification Name:	Resin, Root Canal Filling
Classification:	Class II, 21 CFR 872.3820
Classification Product Code:	KIF

4. Predicate Device:

Well-RootTMST (K170950) by VERICOM Co., Ltd.

5. Device Description:

One-Fil is a convenient premixed ready-to use, injectable calcium silicate composition which requires the presence of water to set and harden. The device is contained in a plastic syringe and the system includes a plunger, disposable tips, and a holder.

6. Indications for Use:

Permanent sealing of root canal



7. Performance Data (Non-Clinical):

The following tests were performed on the subject device and the test results support that the subject device is substantially equivalent to the predicate devices.

- Performance Tests in accordance with ISO 6876 (Appearance, Volume, Packaging, Flow Setting time, Film thickness, Solubility, Radiopaque)
- pH Test
- Biocompatibility Tests in accordance with ISO 10993-3, 5, 6, 10, 11 and USP 34,151>
- Shelf Life Test

8. Substantial Equivalence

8.1. Comparison Chart

	Subject Device	Primary Predicate Device
Trade name	One-Fil	Well-Root™ST
Manufacturer	Mediculs Co.,Ltd	VERICOM Co., Ltd.
510K Number	-	K170950
Product Code	KIF	KIF
Indications for Use	Permanent sealing of root canal	Permanent sealing of root canal
Image		
Raw materials	Insoluble, radiopaque material based on a calcium silicate compound	Insoluble, radiopaque material based on a calcium aluminosilicate compound

Principle of operation	One-Fil is an insoluble, radiopaque material which sets and hardens with moisture providing from dentin tubules during hydration reaction. One-Fil is packaged in a preloaded syringe and is supplied with disposable tips.	WellRoot™ ST is an insoluble, radiopaque material which sets and hardens with moisture providing from dentin tubules during hydration reaction. Well-Root™ST is packaged in a preloaded syringe and is supplied with disposable tips.
Performance Standards Conformance	Conformed to ISO 6876	Conformed to ISO 6876
Biocompatibility	Yes	Yes
Use	Prescription / Hospital	Prescription / Hospital
Delivery form	Single paste	Single paste
Sterility	Non-sterile	Non-sterile

8.2. Substantial Equivalence Discussion

One-Fil has the same intended use as the predicate devices: Well-Root™ST (K170950) by VERICOM Co., Ltd. The indication of the statement of the subject device is more simplified than the predicate devices but it does not contain new indications.

All of the devices confirm to ISO 6876 and are provided non-sterile. Both One-Fil and Well-Root™ ST are premixed ready-to-use injectable white hydraulic cement paste. The differences between One-Fil and Well-Root™ ST are raw materials. However, performance test according to ISO 6876 and biocompatibility tests according to ISO 10993 demonstrate that the difference does not raise a question in safety and effectiveness. We conclude that One-Fil is substantially equivalent to the predicate device.

9. Conclusion:

Based on the information submitted herein, MEDICLUS CO., LTD. concludes that the One-Fil is substantially equivalent to the predicate device.