August 22, 2025

Mediclus Co., Ltd.
Ku Da-Hyeon
Regulatory Affairs Team Manager
No. 1210, 134 Gongdan-ro, Heungdeok-gu
Cheongju-si, 28576
SOUTH KOREA

Re: K251884
Trade/Device Name: One-Fil Putty Injectable
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: July 29, 2025
Received: July 29, 2025

Dear Ku Da-Hyeon:

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
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.	K251884

Please provide the device trade name(s).

One-Fil Putty Injectable

Please provide your Indications for Use below.

1. Furcation or root perforation treatment via canal
2. Furcation or root perforation treatment via surgical
3. Internal reabsorption treatment via canal or surgical
4. External reabsorption treatment
5. Retrofilling in parendodontic surgery
6. Direct and Indirect pulp capping
7. Apexification
8. Apexogenesis and Pulpotomy

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)

510(k) Summary - K252884

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

Date: 22/08/2025

1. Submitter/Contact Person

Da-Hyeon, Ku
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
Email: ra@mdclus.com

2. U.S Agent

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160, Irvine CA 92612
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: One-Fil Putty Injectable
- Common Name: Dental root canal filling material
- Classification Name: Root canal filling resin
- Product Code: KIF
- Classification regulation: 21 CFR 872.3690

4. Predicate Device:

One-Fil Putty by MEDICLUS Co., Ltd. (K243353)

5. Description:

One-Fil Putty Injectable is a premixed material intended for permanent root canal filling. It is based on a tricalcium silicate composition, which undergoes setting and hardening in the presence of moisture.
The product is packaged in a paper box with four syringes in a vinyl packaging, and the contents in the glass syringe are white paste type.

6. Indication for use:

1. Furcation or root perforation treatment via canal
2. Furcation or root perforation treatment via surgical
3. Internal reabsorption treatment via canal or surgical
4. External reabsorption treatment
5. Retrofilling in parendodontic surgery
6. Direct and indirect pulp capping
7. Apexification
8. Apexogenesis and Pulpotomy

7. Basis for Substantial Equivalence

7.1. Comparison Chart

	Subject Device	Predicate Device
Trade name	One-Fil Putty Injectable	One-Fil Putty
Manufacturer	MEDICLUS Co., Ltd.	MEDICLUS Co., Ltd.
510K Number	K251884	K243353
Product Code	KIF	KIF
Indications for Use	1. Furcation or root perforation treatment via canal 2. Furcation or root perforation treatment via surgical 3. Internal reabsorption treatment via canal or surgical 4. External reabsorption treatment 5. Retrofilling in parendodontic surgery 6. Direct and indirect pulp capping 7. Apexification 8. Apexogenesis and Pulpotomy	1. Furcation or root perforation treatment via canal 2. Furcation or root perforation treatment via surgical 3. Internal reabsorption treatment via canal or surgical 4. External reabsorption treatment 5. Retrofilling in parendodontic surgery 6. Direct and indirect pulp capping 7. Apexification 8. Apexogenesis and Pulpotomy
Image		
Raw materials	Zirconium oxide 40%, Tricalcium aluminate compounds 42%, Hydrophilic polymer 18% (Thickening agents)	Zirconium oxide 40%, Tricalcium aluminate compounds 42%, Hydrophilic polymer 18% (Thickening agents)
Principle of operation	The One-Fil Putty Injectable is a premixed ready-to use, injectable bioceramic root canal filling material. The setting of the material occurs via hydration of tricalcium silicate. It is used for root filling or pulp capping, where a physical seal is required.	The One-Fil Putty is a premixed ready-to use, bioceramic root canal filling material. The setting of the material occurs via hydration of tricalcium silicate. It is used for root filling or pulp capping, where a physical seal is required.
Performance Standards Conformance	Conformed to ISO 6876	Conformed to ISO 6876
Biocompatibility	Yes	Yes

Use	Prescription / Hospital	Prescription / Hospital
Delivery form	Single flowable type	Single paste
Curing time	≤ 1hour	≤ 1hour
Performance Specifications	Curing Time: 54 min pH: 13.06 Radiopacity: 9.20 Solubility: 1.1%	Curing Time: 53 min pH: 12.79 Radiopacity: 10.81 Solubility: 1.3%

7.2. Substantial Equivalence Discussion

One-Fil Putty Injectable is substantially equivalent to a predicate device, One-Fil Putty (K243353), by MEDICLUS Co., Ltd. in terms of indications for use, base raw material, physical properties and technological characteristics. Both One-Fil Putty Injectable and One-Fil Putty are ready-to-use paste.

The differences between One-Fil Putty Injectable and One-Fil Putty are particle size of raw material. However, performance tests were conducted in accordance with ISO 6876. Biocompatibility was addressed using FDA's Biocompatibility Guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices − Part 1: Evaluation and testing within a risk management process and ISO 7405 Dentistry − Evaluation of biocompatibility of medical devices used in dentistry.

Based on the information we provided herein, we conclude that One-Fil Putty is substantially equivalent to the predicate device.

8. Non-Clinical Testing

- Performance Tests including Characteristics, Volume, Packing, Curing time, Solubility, pH, Radioactive Impermeable in accordance with ISO 6876.

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.