March 14, 2025

Mediclus Co., Ltd.
% Priscilla Chung
Official Correspondent
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine, California 92612

Re: K243353
Trade/Device Name: One-Fil Putty
Regulation Number: 21 CFR 872.3820
Regulation Name: Root canal filling resin
Regulatory Class: Class II
Product Code: KIF
Dated: October 29, 2024
Received: October 29, 2024

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.

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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OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

K243353

Device Name

One-Fil Putty

Indications for Use *(Describe)*

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

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."

K243353

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: ___Feb 5, 2025___

1. Applicant / Submitter:

MEDICLUS CO., LTD.
No. 1210, 134 Gongdan-ro, Heungdeok-gu,
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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 Putty
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:

BIO-C REPAIR (K180185) by MEDICLUS Co., Ltd.

5. Device Description:

One-Fil putty is a permanent root canal filling repair material with tricalcium aluminate compound that are premixed and designed to be convenient for use. It is hardened by moisture, has characteristics of adhesion and workability.
The product is packaged in a paper box with one or two syringes in a tray, and the contents in the glass syringe are white paste type.

6. 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

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 (Foreign substance, Packaging, Setting time, Solubility, Radiopaque)

No	Test Item	Test Standard
1	Foreign substance	ISO 6876:2012(E) 5.1
2	Volume	-
3	Packaging	ISO 6876:2012(E) 6.3
4	Setting time	ISO 6876:2012(E) 5.4
5	Solubility	ISO 6876:2012(E) 5.6
6	Radio-opacity	ISO 6876:2012(E) 5.7 ISO 13116:2014
7	Elution, pH Test	-

- Volume, pH Test
- Biocompatibility Tests in accordance with ISO 10993-5, 10, 11
- Shelf Life Test

8. Substantial Equivalence

8.1. Comparison Chart

		Subject Device	Predicate Device	Equivalence evaluation
Manufacturer		MEDICLUS CO., LTD.	Angelus Industria de Produtos Odontologicos S/A	-
Product Name		One-Fil Putty	BIO-C REPAIR	-
510k#		-	K180185	-
Material		- Zirconium oxide 40% - Tricalcium aluminate compounds 42% - Hydrophilic polymer 18% (Thickening agents)	- Zirconium oxide - Calcium silicates - Calcium oxide - Silicon oxide - Iron oxide - Dispersing agent	
Curing type		Self-Cure (moisture required)	Self-Cure (moisture required)	same
Indications for Use Statement		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	same
Technological Characteristics	**Standard**	ISO 6876	ISO 6876	same
	Foreign substance	No foreign matter	-	
	Volume	1.77%	-	
	Packaging	There was no damage or cracks in the product, the mixing of foreign substances, or other harmful defects in use	-	
	Setting time	53 min	90-120 minutes	
	Solubility	1.3%	-	
	Radio-opacity	Radiopacity of 3mm aluminum More than that (Radio-opacity=10.81)	~ 7 mm AI	

	pH	12.79	12.5	
Biocompatibility		Using ISO 10993 series Biocompatible	Using ISO 10993 series Biocompatible	same
Sterile		Non-sterile	Non-sterile	
Delivery method		Delivery system: Syringe Weigh: 0.5g , 0.25g Units per Pack: 0.5g x 4, 0.25 x 4, 0.25 x 2	Delivery system: Syringe Weigh: 0.5g Units per Pack: 4 Accessories : tips	
Shelf-Life		2 years	2 years	

8.2. Substantial Equivalence Discussion

The subject device and the predicate device have the same intended use and same technological characteristics and are made of similar materials. They have the same range of physical and chemical properties. The subject and predicate devices are packaged in similar materials and use similar methods of application. Any differences in specific components do not raise new issues of safety or efficacy as both devices confirms to ISO 6876 for performance and ISO 10993 for safety to achieve the indications for use.

9. Conclusion:

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