



July 21, 2026

Mediclus Co., Ltd.
Ku Da Hyeon
Official Correspondent
1210, 134, Gongdan-Ro, Heungdeok-Gu
Cheongju-Si, 28576
REPUBLIC OF KOREA

Re: K261728
Trade/Device Name: One-Fil LC
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium hydroxide cavity liner
Regulatory Class: Class II
Product Code: EJK
Dated: May 26, 2026
Received: May 26, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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

510(k) Number (if known)

K261728

Device Name

One-Fil LC

Indications for Use (Describe)

One-Fil LC is indicated for lining and basing applications under dental restorations.

One-Fil LC is also indicated for direct pulp capping.

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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510(k) Summary

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

Date: May 22, 2025

1. Submitter/Contact Person

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3. Device

- Trade Name: One-Fil LC
- Common Name: Cavity Liner/Base
- Classification Name: Liner/base, Dental Cement
- Product Code: EMA
- Classification regulation: 21 CFR 872.3275

4. Predicate Device:

3M VitCal Liner/Base by 3M ESPE Dental Products. (K230270)

5. Description:

One-Fil LC is a light-cured, calcium silicate-based pulp protectant and cavity liner intended for use in restorative dental procedures. The device is applied to dentin surfaces in deep cavities, including areas in close proximity to the pulp or small pulpal exposures, prior to placement of restorative materials.

The device contains calcium silicate and bioactive glass components. Following placement, the material releases calcium and hydroxyl ions and forms a physical barrier layer at the cavity interface. The device is intended to protect the pulpal area and provide insulation between the tooth structure and overlying restorative materials.

6. Indication for use:

One-Fil LC is indicated for lining and basing applications under dental restorations.

One-Fil LC is also indicated for direct pulp capping.

7. Basis for Substantial Equivalence

7.1. Comparison Chart

		Subject Device	Predicate Device	Equivalence evaluation
Manufacturer		MEDICLUS Co., Ltd.	3M ESPE	-
Product Name		One-Fil LC	3M VitCal Liner/Base	-
510k#		-	K230270	-
Product Code		EMA	EMA	-
Material		Calcium silicate, Bioglass, Bis-GMA, PEGDMA	Portland cement, Silane-treated silica, Methacrylate polymer, photoinitiators	Similar
Curing type		Light-curing	Ligh-curing	Same
Indications for Use Statement		One-Fil LC is indicated for lining and basing applications under dental restorations. One-Fil LC is also indicated for direct pulp capping.	3M VitCal Liner/Base is indicated for lining and basing applications under dental restorations. 3M VitCal Liner/Base is also indicated for direct pulp capping.	Same
Intended User		Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Same
Techno logical	Standard	ISO 4049 and ISO 6876	ISO 4049 and ISO 6874	Similar
	Depth of cure	≥ 1.0 mm	-	

Characteristics	Film thickness	$\leq 50 \mu\text{m}$	-	
	Flexural strength	$\geq 10 \text{ MPa}$	$> 10 \text{ MPa}$	
	Calcium release	$\geq 100 \text{ ppm}$	$> 0 \mu\text{g/g}$	
Biocompatibility		Biocompatible	Biocompatible	Same
Dispensing System		Intra-oral, syringe with single-use tips	Intra-oral, multi-nuit micro-mix syringe with single-use tips	Similar
Period of Use		Permanent	Permanent	Same
Shelf-Life		2 years	3 years	Similar

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, Volume, Packaging, Sensitivity to the light, Color stability, Depth of cure, Radio-opacity, Film thickness, Flowability, Flexural strength, pH, Calcium release amount (10 days) in accordance with ISO 4049, ISO 6876.
- Biocompatibility Tests
 - ISO 10993-1 Biological evaluation of medical devise – Part 1: Evaluation and testing within a risk management process
 - ISO 10993-5:2009, Tests for in vitro cytotoxicity
 - ISO 10993-23:2021, Tests for irritation
 - ISO 10993-10:2021, Tests for skin sensitization
 - ISO 10993-11:2017, Tests for systemic toxicity

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.