February 27, 2026

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

Re: K253797
Trade/Device Name: One-Stop
Regulatory Class: Unclassified
Product Code: MVL
Dated: November 27, 2025
Received: November 28, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 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,
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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.	K253797

Please provide the device trade name(s).

One-Stop

Please provide your Indications for Use below.

One-Stop is intended for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, taking an impression, cementation, and cavity preparation.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary- K253797

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

Date: November 27, 2025

1. Submitter/Contact Person

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3. Device

- Trade Name: One-Stop
- Common Name: Gingival Retraction Paste
- Classification Name: Unclassified
- Product Code: MVL
- Classification regulation: 21 CFR

4. Predicate Device:

GingiDent Gingival Retraction Paste by Pac-Dent International, Inc (K162662)

5. Description:

One-Stop is a paste-type topical pre-impression agent intended to provide gingival retraction and hemostasis. The product contains aluminum chloride, which functions as an astringent. Its paste consistency allows controlled placement in the target area, and it can

be removed by rinsing with water after use.

6. Indication for use:

One-Stop is intended for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, taking an impression, cementation, and cavity preparation.

7. Basis for Substantial Equivalence

7.1. Comparison Chart

	Subject Device	Predicate Device	Equivalence evaluation
Manufacturer	MEDICLUS Co., Ltd.	Pac-Dent International, Inc.	-
Product Name	One-Stop 	GingiDent Gingival Retraction Paste 	-
510k#	K253797	K162662	-
Product Code	MVL	MVL	
Material	Aluminum chloroide-hexahydrate Propylene glycol Water Etc.,	Aluminum Chloride-Hexahydrate Kaolin Water	Similar
Application time	2~3 minutes	2 minutes	Same
Indications for Use Statement	One-Stop is intended for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, taking an impression, cementation, and cavity preparation.	For the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, taking an impression, cementation and cavity preparation.	Same

Intended User		Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Same
Technological Characteristics	**pH**	0.7	3.22	Similar
	Aluminum chloride hexahydrate	18.3%	16.42%	
	Flow	11 mm	995,000 (cP)	
Biocompatibility		Biocompatible	Biocompatible	Same
Delivery method		• Delivery System: Syringe • Weight: 0.85g • Disposable tip	• Delivery System: Syringe • Weight: 0.7g • Disposable tip	Similar
Period of Use		Limited exposure(A) (< 24 hours)	Limited exposure(A) (< 24 hours)	Same
Shelf-Life		2 years	2.8 years	Same

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, Weight, Packaging, pH, Flow, Quantitative in accordance with 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, test for in vitro cytotoxicity
  - ISO 10993-23:2021, Tests for irritation (Replaced with a pH test)
  - ISO 10993-10:2021, Tests for skin sensitization

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.