May 14, 2026

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

Re: K260485
Trade/Device Name: Any-Etch
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: February 13, 2026
Received: February 13, 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260485

Please provide the device trade name(s).

Any-Etch

Please provide your Indications for Use below.

- Pretreatment etchant before resin (help to having a strong bonding strength between resin and teeth)
- Remove smear layer of dentin and enamel
- Pretreatment etchant before sealant (help to having a strong bonding strength between resin and teeth)

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

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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 13, 2026

1. Submitter/Contact Person

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3. Device

- Trade Name: Any-Etch
- Common Name: Dental Etchant
- Classification Name: Agent, Tooth Bonding, Resin
- Product Code: KLE
- Classification regulation: 21 CFR 872.3200

4. Predicate Device:

FineEtch by Spident Co., Ltd. (K242675)

5. Description:

Any-Etch is a phosphoric acid-based dental etching gel intended for professional use on enamel and dentin surfaces to enhance the adhesion of resin-based restorative materials.

6. Indication for use:

- Pretreatment etchant before resin (help to having a strong bonding strength between resin and teeth)
- Remove smear layer of dentin and enamel
- Pretreatment etchant before sealant (help to having a strong bonding strength between sealant and teeth)

7. Basis for Substantial Equivalence

7.1. Comparison Chart

	Subject Device	Predicate Device	Equivalence evaluation
Manufacturer	MEDICLUS Co., Ltd.	Spident Co., Ltd.	-
Product Name	Any-Etch 	FineEtch 	-
510k#		K242675	-
Product Code	KLE	KLE	
Material	Phosphoric acid	Phosphoric acid(H_3PO_4)	Similar
Application time	10 ~ 15 sec	15 ~ 20 sec	Similar
Indications for Use Statement	1. Isolate the tooth and prepare the cavity. 2. Remove moisture from the tooth and cavity. 3. Apply Any-Etch to the tooth surface and cavity, then wait for approximately 10–15 seconds. (Enamel : 15 seconds / Dentin : 10 seconds) 4. Remove Any-Etch using suction. 5. Rinse thoroughly with an	1. Clean and dry the cavity. Rubber dam (Finedam, Spident) is recommended for isolation. 2. Prepare the cavity. 3. Etch entire cavity with FineEtch (Enamel 20 seconds, Dentin 15 seconds) 4. Remove etching gel by suction. Rinse for 15 seconds.	Same

		excessive amount of water to ensure no residue remains. 6. When applying the bonding agent, ensure that saliva or blood does not contaminate the treated area.		
Intended User		Licensed Dentist or Dental Professional	Licensed Dentist or Dental Professional	Same
Technological Characteristics	**pH**	0.7	0.1 – 0.4	Similar
	Flow (mm)	17.48	-	
	Corrosion	Corrosed	Corrosed	
Biocompatibility		Biocompatible	Biocompatible	Same
Delivery method		• Delivery system: Syringe • Volume: 3ml • Disposable tip	• Delivery system: Syringe • Volume: 3ml • Disposable tip	Similar
Period of Use		Limited exposure (A) (< 24 hours)	Limited exposure (A) (< 24 hours)	Same
Shelf-Life		3 years	2 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 tests

Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'

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.