November 1, 2024

Spident Co., Ltd.
Eunok Choi
RA Manager
203 & 312, Korea Industrial Complex, 722
Gojan-Dong, Namdong-Gu
Incheon, Incheon 405-821
Korea, South

Re: K242675
Trade/Device Name: FineEtch (FineEtch-10 1.2ml, FineEtch-10 5ml, FineEtch-37 1.2ml FineEtch-37 5ml, FineEtch 37% 1.2ml 20ea pack)
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin tooth bonding agent
Regulatory Class: Class II
Product Code: KLE
Dated: September 3, 2024
Received: September 6, 2024

Dear Eunok Choi:

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

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)*

K242675

Device Name

FineEtch (FineEtch-10 1.2ml, FineEtch-10 5ml, FineEtch-37 1.2ml FineEtch-37 5ml, FineEtch 37% 1.2ml 20ea pack)

Indications for Use *(Describe)*

• 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)

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) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: September 20, 2024

1. Company and Correspondent making the submission:

Company Name : SPIDENT CO., LTD.
Address : 203 & 312, Korea Industrial Complex, 722, Gojan-Dong, Namdong-Gu, Incheon, Korea 405-821
Tel : +82-32-821-0071
Fax : + 82-32-821-0074
Company Contact : Eunok Choi/RA Manager

2. Device Name and Classification

Device Trade Name : FineEtch (FineEtch-10 1.2ml, FineEtch-10 5ml, FineEtch-37 1.2ml FineEtch-37 5ml, FineEtch 37% 1.2ml 20ea pack)
Common name : Dental etchant
Classification name : Resin tooth bonding agent [CFR 872.3200]
Product code : KLE
Class : II

3. Predicate Devices (Legally Marketed Devices)

The predicate devices for FineEtch is :

- **K-ETCHANT GEL,** KURARAY MEDICAL INC., K062409

4. Device Description:

FineEtch - 10, 37 is a phosphoric acid (H3PO4) semi-gel-type agent intended for use on dentin and enamel. FineEtch will effectively remove the smear layer and help successful bonding.

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5. Indications 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)

6. Indications for Use Comparison

The indication for use of the subject device are all included in the indication for use of the predicate device (Etching the enamel and dentin for adhesive restorations). There are some differences in expression, but they both can be used as a pretreatment before resin and sealant. Also, both can be used to remove smear layer of dentin and enamel.

7. Technological Comparison

Principle Operation, Biocompatibility, Application Area, Target Population of subject device and predicate device are the same. The performance results of the subject device and predicate device is similar.
Also, both subject device and predicate device have the similar intended operator.
In case of storage condition, both products have similar limit of temperature.
Therefore, FineEtch is substantially equivalent with predicate device, K-ETCHANT GEL, and at least as safe and effective as the predicate device.

8. Performance Testing-Non Clinical tests

pH, viscosity, shape retention functions and etching effect test were conducted for non clinical tests. The performance of FineEtch is compared with K-Etchant gel (predicate device) and Scotchbond™ Universal Etchant (other dental etchant).
The test results showed that the subject device is as good as the predicate device. Therefore, It can be considered that our subject device is as safe, effective and performs as well as or better than the predicate device and other dental etchant in the market.

9. Performance Testing-Clinical tests

Not Applicable

10. Conclusion

Based on a comparison of subject device, FineEtch (SPIDENT CO., LTD.) and predicate device, K-ETCHANT GEL (KURARAY MEDICAL INC.), it is confirmed that the subject device is substantially equivalent to predicate device.