December 20, 2024

Rizhao HuGe Biomaterials Company, Ltd.
Maggie Zheng
Regulatory Affairs Manager
No.2 North Zhaoyang Road, District of Donggang
Rizhao City, 276800
CHINA

Re: K242530
Trade/Device Name: HF-Etchant Hydrofluoric Acid Etching Gel
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE, EIH, PME
Dated: August 24, 2024
Received: August 26, 2024

Dear Maggie Zheng:

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)*

K242530

Device Name

HF-Etchant Hydrofluoric Acid Etching Gel

Indications for Use *(Describe)*

Used for extraoral etching of various types of resin bonded porcelain/ceramic restorations (veneers, crowns, and inlays) prior to the bonding and cementation procedure.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K242530

510 (k) Summary

This summary of 510(k) for the subjective device equivalence information is being submitted in accordance with the requirements of 21 C.F.R. 807.92.

1. **Date Summary Prepared:** December 19, 2024

2. **Submitter Information:**

Owner's Name	Rizhao HuGe Biomaterials Company, Ltd.
Address	No.2 North Zhaoyang Road, District of Donggang, Rizhao City, Shandong Province, China 276800
Telephone	0086 633 2277268
Fax	0086 633 2277298
Contact Person	Ms. Maggie Zheng
Contact Title	Regulatory Affairs Manager
E-mail	zhengxy@hugedent.com

3. **Device Name**

Trade name: HF-Etchant Hydrofluoric Acid Etching Gel
Common name: Hydrofluoric Acid Etching Gel
Classification name: Resin Tooth Bonding Agent (21 CFR 872.3200)
Regulatory Class: II
Product Code: KLE, EIH, PME

4. **Predicate Device Information**

Owner/Operator	Device Trade Name	510 (k) No.	Product Code
Liaoning Upcera Co., Ltd	Ceramic Etchant (HF-5 and HF-9)	K240153	KLE, EIH, PME

No reference device were used in this submission.

5. **Description of Device**

HF-Etchant Hydrofluoric Acid Etching Gel is composed of water, hydrofluoric acid, thickening agent and pigment. It is a water soluble and miscible flowable gel. Using a disposable

dispensing tip, the Hydrofluoric acid etching gel can be directly applied onto the porcelain/ceramic surface. Its color is red, which can be identified easily on tooth or a repairing surface with contrast.

HF-Etchant Hydrofluoric Acid Etching Gel is delivered in syringes.

6. Indications for Use

Used for extraoral etching of various types of resin bonded porcelain/ceramic restorations (veneers, crowns, and inlays) prior to the bonding and cementation procedure.

7. Technological Characteristics Comparison

All components of the subject device are based upon industry well-known chemistry. The following table shows the significant technological characteristics for the subject device and indicates the following similarities and differences with the predicate device.

Technological Characteristics Comparison Table		
Technological Characteristics	Subject device (HF-Etchant Hydrofluoric Acid Etching Gel)	Predicate device K240153
Composition of Materials	Water, hydrofluoric acid, thickening agent and pigment.	Water, hydrofluoric acid, thickening agent and pigment.
Indications of Use	Used for extraoral etching of various types of resin bonded porcelain/ceramic restorations (veneers, crowns, and inlays) prior to the bonding and cementation procedure.	Ceramic Etchant is intended for etching the porcelain veneers, crowns, and inlays extraorally. It is also used for pretreating the porcelain veneers, crowns, and inlays extraorally before bonding.
Clinical condition	Conditioning of porcelain/ceramic surface	Conditioning of porcelain/ceramic surface
Time for use	10-60 seconds	20-40 seconds
Water Solubility	Soluble	Soluble
Contact with human body	Etching in vitro	Etching in vitro
Prescription/over-the-counter use	Prescription	Prescription
Physical form	Gel	Gel
Delivery form	Syringe	Syringe
Physical Properties	The subject device and the predicate device have substantially equivalent physical properties as they all conform to HUGE SOP.	

The technological characteristics of the subject device are very similar to those of the predicate device. The subject device is a similar product, manufactured with similar materials and used in the same way by the same types of users and patient populations. The subject device and the predicate device have minor difference in Composition of Materials. However, the difference does not affect the intended use or substantial equivalence. Besides, other comparison items such as Clinical condition, Time for use, Water Solubility, Contact with human body, Physical form, Delivery form and Physical Properties, etc. are the same or very similar. And both of the subject device and the predicate device are supplied for prescription use.

8. Summary of Non-clinical testing

Through real-time stability testing, the shelf life of the subject device is reliable and effective within 2 years.

The physical properties of the subject device, including Thermostability, Hydrofluoric acid content, Rotational viscosity value and pH value, were determined and tested according to Internal standard SOP of the company, and the test results demonstrated the qualification and substantial equivalence when compared to the predicate device.

Additionally, the subject device is substantially equivalent to the predicate device that has been legally marketed already and with no clinical adverse events. The compositions of the subject device do not contain any non-conventional chemicals compared to the legally marketed predicate device. According to International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", the subject device does NOT contact the patient’s body directly or indirectly, and Biocompatibility Evaluation Endpoints are not applicable and biocompatibility tests are not required accordingly. And the biocompatibility analysis is sufficient to prove the safety of the subject device.

9. Summary of Clinical testing

Clinical test is not applicable.

10. Conclusions

Based on the indications for use, technological characteristics, performance testing and comparison to the predicate device, the subject device has been shown to be safe and effective for its intended use and the minor differences in composition of the predicate device affecting neither the general intended use nor substantial equivalence. Rizhao HuGe Biomaterials Company, Ltd. concludes that the subject device is substantially equivalent to the predicate

device described herein.