September 12, 2022

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

Re: K221450
Trade/Device Name: Phosphoric Acid Etching Gel
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: July 8, 2022
Received: July 14, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221450

Device Name
Phosphoric Acid Etching Gel

Indications for Use *(Describe)*

Used for etching of tooth enamel and/or dentin prior to the applications of bonding direct filling, repairing or enamel surface coating materials, as well as cementation of indirect restorations such as crowns, bridges, inlays/onlays, veneers, posts, splints, orthodontic brackets, etc. made of resin composites, porcelains/ceramics, metals and their combinations. Can also be used for cleaning of restoration surfaces prior to repairing or cementation.

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.

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K221450
005_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:** July 8, 2022

2. Submitter Information:

Name	Rizhao HuGe Biomaterials Company, Ltd.
Address	No.2 North Zhaoyang Road, District of Donggang, Rizhao City, Shandong Province, China 276800
Telephone	086-633-2277268
Contact Person	Ms. Maggie Zheng
Contact Title	Regulatory Affairs Manager
E-mail	zhengxy@hugedent.com

3. Device Name

Trade name: Phosphoric Acid Etching Gel

Common name: Phosphoric Acid Etchant

Classification name: Agent, Tooth bonding, Resin (21 CFR 872.3200)

Regulatory Class: II

Product Code: KLE

4. Predicate Device Information

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Predicate
BISCO, INC.	Bisco Etchants	K101485	KLE	Primary

The predicate device has not been subject to a design-related recall.

5. Description of Device

Patient populations: Patients need dental restorations in dental therapy.

Target user group: Use by health care professional or dentist.

Phosphoric Acid Etching Gel is a flowable gel with excellent water solubility and miscibility.

Using a disposable dispensing tip, Phosphoric Acid Etching Gel can be directly applied onto the tooth surface. Its color is blue, which can be identified easily on tooth or a repairing surface with contrast. Phosphoric Acid Etching Gel is used as an auxiliary material in the dental bonding procedure followed by the use of Light Cure Dental Adhesive.

6. Indications for Use

Used for etching of tooth enamel and/or dentin prior to the applications of bonding direct filling, repairing or enamel surface coating materials, as well as cementation of indirect restorations such as crowns, bridges, inlays/onlays, veneers, posts, splints, orthodontic brackets, etc. made of resin composites, porcelains/ceramics, metals and their combinations. Can also be used for cleaning of restoration surfaces prior to repairing or cementation.

7. Summary of Physical and Chemical Properties Tests

- Chemical Composition:

The main component of the subject device is phosphoric acid.

- Technological characteristics:

The device has the same technological characteristics as the predicate device (Bisco Etchants).

- Properties:

The device has comparable physical and chemical properties as the predicate device.

- Applications:

The device has similar indications for use as the sum of the predicate devices: Used for etching of tooth enamel and/or dentin prior to the applications of bonding direct filling, repairing or enamel surface coating materials, as well as cementation of indirect restorations such as crowns, bridges, inlays/onlays, veneers, posts, splints, orthodontic brackets, etc. made of resin composites, porcelains/ceramics, metals and their combinations. Can also be used for cleaning of restoration surfaces prior to repairing or cementation.

8. Technological Characteristics

All components of the Phosphoric Acid Etching Gel are based upon industry well-known chemistry. Phosphoric Acid Etching Gel is mainly composed of phosphoric acid. Phosphoric Acid Etching Gel creates microscopic spaces in enamel (increasing surface roughness) allowing

the bonding agent/adhesive flows into, so as to promote the bonding process (micromechanical retention).

The following table shows the technological characteristics for the subject device and indicates the following similarities and differences with the predicate device:

<table>
<tr><td rowspan="2">Comparison Items</td><td colspan="6">Subject Device</td><td>Predicate Device</td></tr>
<tr><td colspan="6" rowspan="2">Phosphoric Acid Etching Gel</td><td>Bisco Etchant</td></tr>
<tr><td>K101485</td></tr>
<tr><td>(1) Regulatory Classifications</td><td colspan="6">Class II</td><td>Class II</td></tr>
<tr><td>(2) Indications for use</td><td colspan="6">Similar</td><td>Similar</td></tr>
<tr><td>(3) Contraindications</td><td colspan="6">Similar</td><td>Similar</td></tr>
<tr><td>(4) Composition of Materials</td><td colspan="6">Mainly phosphoric acid</td><td>Mainly phosphoric acid</td></tr>
<tr><td>(5) Physical Properties</td><td colspan="7"><table>
<tr><td>Inspection standard</td><td colspan="5">“Phosphoric Acid Etching Gel Final Inspection Standard”
HGD/QT-PhAE-02-04 (ie., YY0769-2009)</td></tr>
<tr><td>Inspection items</td><td>Surface</td><td>Thermostability</td><td>Phosphoric acid content</td><td>PH value</td><td>Shear bond strength</td></tr>
<tr><td>Technical requirements</td><td>Acid etching gel should have obvious color, uniform texture and no impurity.</td><td>When placed at (50±1) ℃ for 24h, no color change, stratification and spillage can be observed.</td><td>The phosphoric acid content is not more than 2% of the indicated value (mass fraction).</td><td><2</td><td>> 20Mpa</td></tr>
<tr><td>Subject device</td><td colspan="5">Qualified</td></tr>
<tr><td>Predicate device</td><td colspan="5">Qualified</td></tr>
</table></td></tr>
<tr><td>(6) Phosphoric acid content</td><td colspan="6">Similar</td><td>Similar</td></tr>
</table>

Comparison Items	Subject Device	Predicate Device
	Phosphoric Acid Etching Gel	Bisco Etchant
		K101485
(7) Labeling	Similar	Similar
(8) Anatomical Site	on teeth	on teeth
(9) Where Used	used in hospital, dental clinic and relevant places	used in hospital, dental clinic and relevant places
(10) Human Factors	Dental professional	Licensed dentist
(11) Design	Similar	Similar
(12) Precautions	Similar	Similar
(13) Standards Met	Similar	Similar
(14) Biocompatibility	Biocompatible	Biocompatible
(15) Sterility	Non-sterile	Non-sterile
(16) Chemical Safety	Similar	Similar
(17) Storage	Similar	Similar
(18) Shelf life	Similar	Similar

As shown above, the both products are mainly composed of phosphoric acid and intended to etching of tooth enamel and/or dentin and cleaning of dental restorative surfaces. Besides, other comparison items such as main component, technical principle, physical form, and physical properties are the same or highly similar.

9. Summary of Biocompatibility

The subject device, Phosphoric Acid Etching Gel, is substantially equivalent to the predicate device that have been legally marketed for decades and with no clinical adverse events. The formulation of the subject device does not contain any non-conventional chemicals compared to the legally marketed predicate device.

Biocompatibility tests were performed fully following the ISO 10993 standards. The test item is Skin Sensitization.

10. Clinical Performance Data

Not applicable. Clinical performance testing has not been performed for the subject device.

11. Conclusions

As with the comparison shown in substantial equivalence discussion, these devices are same or similar in almost all aspects. The details of physical properties are slightly different, but these two devices are in compliance with the relevant standards.

It can be seen that the minor differences between the new device and the predicate device are not of significance and do not raise questions of safety and effectiveness as compared to the predicate device. We conclude that Phosphoric Acid Etching Gel is substantially equivalent to the predicate device described herein.