September 25, 2020

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

Re: K201787
Trade/Device Name: Light Cure Dental Adhesive
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: July 17, 2020
Received: July 27, 2020

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)*
K201787

Device Name
Light Cure Dental Adhesive

Indications for Use *(Describe)*
Light Cure Dental Adhesive can be used as a strict self-etch dental bonding agent, or in combination with the traditional total etch or enamel etch procedures:
- Direct bonding under a light-cured composite or compomer fillings/resin modified glass ionomer restoratives;
- Repair of dental restorations of ceramic, composites and/or metal alloys;
- Indirect dental restorations cementation applications in combination with resin cement for cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers, dental posts and other restorations made from materials of metals/alloys, mental-ceramic, all-ceramic and/or porcelain, composites, and their combinations.

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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K201787

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:** September 25, 2020

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	Mrs. Maggie Zheng
Contact Title	Regulatory Affairs Manager
E-mail	zhengxy@hugedent.com

3. **Device Name**

Trade name: Light Cure Dental Adhesive

Common name: Dental Adhesive

Classification name: Resin Tooth Bonding Agent (21 CFR 872.3200)

Regulatory Class: II

Product Code: KLE

4. **Predicate Device Information**

Table 1: Predicate Device Information

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Predicate
BISCO, INC.	DREAMBOND	K112118	KLE	Primary

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

No reference devices were used in this submission.

5. **Description of Device**

Light Cure Dental Adhesive is a universal self-etch visible light curable dentine bonding agent specifically designed for meeting all your bonding needs. It is not only for direct bonding under a dental composite restorative or a resin modified glass ionomer cement restorative, but also for all indirect dental restoration cementation applications, either used as a strict self-etch dental bonding agent, or in combination with the traditional total etch or enamel etch procedures. In all of those cases, this dental bonding agent will give you exceptional results and predicting a reliable treatment outcome.

6. Indications for Use

Light Cure Dental Adhesive can be used as a strict self-etch dental bonding agent, or in combination with the traditional total etch or enamel etch procedures:

- Direct bonding under a light-cured composite or compomer fillings/resin modified glass ionomer restoratives;
- Repair of dental restorations of ceramic, composites and/or metal alloys;
- Indirect dental restorations cementation applications in combination with resin cement for cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers, dental posts and other restorations made from materials of metals/alloys, mental-ceramic, all-ceramic and/or porcelain, composites, and their combinations.

7. Summary of Physical and Chemical Properties Tests

Test standards and methods based on ISO 29022: 2013 (Dentistry - Adhesive - Notched-edge sheer bond strength test) and internal final inspection standard of Rizhao HuGe Biomaterials Company, Ltd.. And the results from testing demonstrate that Light Cure Dental Adhesive is substantially equivalent to the predicate device.

8. Technological Characteristics

All components of the subject device are based upon industry well-known chemistry. The etch methods of the subject device and predicate device covered the flexibility for total-, self- and selective-etch procedures. The following table shows the significant technological characteristics for the subject device and indicates the following similarities and differences with the predicate device:

Table 4: Technological Characteristics Comparison Table

Technological Characteristics	Subject device (Light Cure Dental Adhesive)	Primary predicate K112118

Method of polymerization	Light Cured	Light Cured
Resin composition	Unfilled, multifunctional methacrylate resin	Unfilled, multifunctional methacrylate resin
Solvent	Ethanol based	Ethanol based
Method of application	Single component adhesive	Single component adhesive
Indications of Use	Light Cure Dental Adhesive can be used as a strict self-etch dental bonding agent, or in combination with the traditional total etch or enamel etch procedures: - Direct bonding under a light-cured composite or compomer fillings/resin modified glass ionomer restoratives; - Repair of dental restorations of ceramic, composites and/or metal alloys; - Indirect dental restorations cementation applications in combination with resin cement for cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers, dental posts and other restorations made from materials of metals/alloys, mental-ceramic, all-ceramic and/or porcelain, composites, and their combinations.	The indications of use of DREAMBOND are: 1. all direct restorations 2. all indirect restorations 3. intra-oral repairs (i.e. repair. of any fixed dental prosthesis containing zirconia, alumina, metals, glass ceramics, tooth structure, and composites) 4. desensitizing/sealing of tooth structure 5. protective varnish for glass ionomer fillings 6. priming of enamel for orthodontic use
Prescription/over-the-counter use	Prescription	Prescription
Etch Method	Total-etch, self-etch and selective-etch procedures	Total-etch, self-etch and selective-etch procedures
Physical Properties	The subject device and the predicate device have substantially equivalent physical property of shear bond strength as they all conform to the specifications set by internal final inspection and the test method equal to ISO 29022:2013.	

9. Summary of Biocompatibility

The new device, Light Cure Dental Adhesive, is substantially equivalent to the predicate devices that have been legally marketed for decades and with no clinical adverse events. The formulation of new device does not contain any non-conventional chemicals compared to the legally marketed predicate device.

We selected our Light Cure Dental Adhesive (6mL) as the representative model in biocompatibility tests. Because our company only has one component formula for this product. The chemical compositions, raw material suppliers, curing method and other technological characteristic in all packing specifications are identical, the difference only depends on the quantity.

The packaging bottle materials used for all packaging specifications are the same, and the packaging method is the same.

Therefore, the packaging specifications differences in the delivery system affect neither the intended use nor substantial equivalence.

Biocompatibility tests were performed fully following the ISO 10993 standards. The test items include Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Subchronic Toxicity and Genotoxicity.

10. Clinical Performance Data

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

11. Conclusions

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the subject device has been shown to be safe and effective for its intended use and the minor differences in indications for use fall within the intended use of the predicate devices 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 devices described herein.