July 25, 2023

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

Re: K230455
Trade/Device Name: Enamel Coating Resin
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit And Fissure Sealant And Conditioner
Regulatory Class: Class II
Product Code: EBC
Dated: April 3, 2023
Received: April 7, 2023

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 -S

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)*
K230455

Device Name
Proseal Enamel Coating Resin

Indications for Use *(Describe)*
Proseal Enamel Coating Resin is a light curing material for sealing the enamel pits and fissures of 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.

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."

K230455

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 21, 2023

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

3. **Device Name**

Trade name: Proseal Enamel Coating Resin

Common name: Dental sealant, pit and fissure sealant

Classification name: Sealant, Pit And Fissure, And Conditioner

Regulatory Class: II

Product Code: EBC

4. **Predicate Device Information**

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Predicate
3M COMPANY	3M™ ESPE™ Clinpro™ Sealant	K992326	EBC	Primary

No reference devices were used in this submission.

5. **Description of Device**

Proseal Enamel Coating Resin is a light-curing fissure sealant and is mainly composed of methacrylate resin, photo initiator system and inorganic fillers. It is packaged in syringes or

bottles.

6. Indications for Use

Proseal Enamel Coating Resin is a light curing material for sealing the enamel pits and fissures of teeth.

7. Summary of Physical Properties Tests

Proseal Enamel Coating Resin is classified as Class 2 sealant in accordance with ISO 6874: 2015. The physical properties were determined and tested according to ISO 6874: 2015 and FDA guidance “Guidance for Industry and FDA Staff Dental Composite Resin Devices -Premarket Notification [510(k)]Submissions Document issued on: October 26, 2005”.

In-vitro bench tests were performed on the Proseal Enamel Coating Resin. The test results indicated that the Proseal Enamel Coating Resin meets the pass/fail criteria and supports substantial equivalence when compared to the predicate device on physical properties. The main test items inlcude depth of cure, flexural strength, shear bonding strength, compressive strength, water sorption, solubility, film thickness and elastic modulus.

The risk analysis of Proseal Enamel Coating Resin was conducted according to ISO 14971 and the residual risk is considered acceptable.

8. Technological Characteristics

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

Technological Characteristics	Subject device	Primary predicate device
	Proseal Enamel Coating Resin(K230455)	3M™ ESPE™ Clinpro™ Sealant(K992326)
Physical Form	Flowable Paste	Flowable Paste
Indications of Use	Proseal Enamel Coating Resin is a light curing material for sealing the enamel pits and fissures of teeth.	3M™ ESPE™ Clinpro™ Sealant is indicated for: Pit and fissure sealant.
Prescription/over-the-counter use	Prescription	Prescription
Color-change technology	The color-change technology is a unique color-change feature. The product (Type	The color-change technology is a unique color-change feature. The product is pink

Technological Characteristics	Subject device	Primary predicate device
	Proseal Enamel Coating Resin(K230455)	3M™ ESPE™ Clinpro™ Sealant(K992326)
	F) is pink when applied to the tooth surface, and changes to an opaque off-white color when exposed to light. The pink color aids the dental professional in the accuracy and amount of material placed during the sealant procedure. When light-cured, the pink sealant will transform to an opaque off-white color. The change of color from pink to opaque off-white is not a cure indicator.	when applied to the tooth surface, and changes to an opaque off-white color when exposed to light. The pink color aids the dental professional in the accuracy and amount of material placed during the sealant procedure. When light-cured, the pink sealant will transform to an opaque off-white color. The change of color from pink to opaque off-white is not a cure indicator.
Curing method	Light cure	Light cure
Delivery form	Syringe or bottle	Syringe or bottle
Physical Properties	The subject device and the predicate device have substantially equivalent physical properties as they all meet the criteria per ISO 6874 and FDA Staff Dental Composite Resin Devices -Premarket Notification [510(k)]Submissions Document issued on: October 26, 2005”.	
FDA-Recognized Standards	ISO 6874; ISO 7405; ISO 10993-1	ISO 6874; ISO 7405; ISO 10993-1

All compositions of the subject device are based upon industry well-known chemistry. The technological characteristics of the subject device are very similar to those of the predicate device, 3M™ ESPE™ Clinpro™ Sealant (K992326). 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 primary predicate device have minor difference in Composition of Materials. However, the difference does not affect the intended use or substantial equivalence, both products are intended for pit and fissure sealant. Besides, other comparison items such as physical form, curing method, delivery form and physical properties, etc. are the same or very similar. And both products are supplied for prescription use.

9. Summary of Biocompatibility

The subject device, Proseal Enamel Coating Resin, is substantially equivalent to the predicate device.

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 on the subject device.

11. Conclusions

Based on the indications for use, technological characteristics, performance testing and comparison to predicate device, the subject device is substantially equivalent to the predicate device described herein.