



November 8, 2024

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

Re: K242749

Trade/Device Name: TopCEM Ceramic Primer Ceramic Coupling Agent
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE, EMA
Dated: September 12, 2024
Received: September 12, 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

Indications for Use

Submission Number (if known)

K242749

Device Name

TopCEM Ceramic Primer Ceramic Coupling Agent

Indications for Use (Describe)

TopCEM Ceramic Primer Ceramic Coupling Agent serves as priming agent and is used to create a durable adhesion between luting composites and glass/oxide ceramic, metal, composite and fiber-reinforced composite restorations.

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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K242749

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:** October 29, 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: TopCEM Ceramic Primer Ceramic Coupling Agent
Common name: Ceramic Coupling Agent
Classification name: Agent, Tooth Bonding, Resin (21 CFR 872.3200)
Regulatory Class: II
Product Code: KLE, EMA

4. **Predicate Device Information**

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Device Type
IVOCLAR VIVADENT, INC.	MONOBOND PLUS	K090826	KLE	Predicate
IVOCLAR VIVADENT, INC.	Monobond Etch & Prime	K150164	KLE	Reference
Rizhao HuGe Biomaterials Company, Ltd.	Dual Cure Resin Cement	K201790	EMA, EBF	

In addition to the predicate device, Monobond Etch & Prime (K150164) and Dual Cure Resin Cement (K201790) are included as reference devices in support of substantial equivalence. The main reason for inclusion of the reference devices, is to support similarities and safety in composition of materials to the subject device, and the other items are not included in the comparison table between the reference devices and the other two devices accordingly. The predicate devices have not been subject to a design-related recall.

5. Description of Device

TopCEM Ceramic Primer Ceramic Coupling Agent is common oral cementation repair auxiliary materials. In the process of using the product, TopCEM Ceramic Primer Ceramic Coupling Agent is placed between the prosthesis and resin adhesives, which can form the bonding layer of tooth tissue - light cure dental adhesive layer - resin cement layer - ceramic coupling agent - prosthesis, so as to achieve better bonding effect. TopCEM Ceramic Primer Ceramic Coupling Agent does not have direct contact with tooth tissue during use.

TopCEM Ceramic Primer Ceramic Coupling Agent is mainly composed of silane coupling agent, acid acrylate and volatile organic solvent.

6. Indications for Use

TopCEM Ceramic Primer Ceramic Coupling Agent serves as priming agent and is used to create a durable adhesion between luting composites and glass/oxide ceramic, metal, composite and fiber-reinforced composite restorations.

7. Technological Characteristics Comparison

All components of the subject device are based upon industry well-known chemistry. The curing mechanism is achieved through polymerization together with a resin cement. The following table shows the significant technological characteristics for the subject device and indicates the following similarities and differences with the predicate and reference devices.

Technological Characteristics Comparison Table				
Technological Characteristics	Subject device K242749	Predicate device K090826	Reference device K150164	Reference device K201790
Composition of Materials	It is mainly composed of silane coupling agent, acid acrylate and volatile	It is mainly composed of silane coupling agent, acid acrylate and volatile	It is mainly composed of ceramic etching	1. Monomer matrix: Methacrylate

Technological Characteristics Comparison Table				
Technological Characteristics	Subject device K242749	Predicate device K090826	Reference device K150164	Reference device K201790
	organic solvent.	organic solvent.	agent, silane coupling agent, acid acrylate and volatile organic solvent.	based 2. Primary Filler(s): Silanated Barium glass filler
Physical Form	Liquid	Liquid	/	
Indications for Use	TopCEM Ceramic Primer Ceramic Coupling Agent serves as priming agent and is used to create a durable adhesion between luting composites and glass/oxide ceramic, metal, composite and fiber-reinforced composite restorations.	Monobond Plus serves as bonding agent and is used to create a durable chemical bond between luting composites and glass/oxide ceramic, metal, composite and fiber-reinforced composite restorations.	/	
Clinical condition	Priming of dental restorations	Priming of dental restorations	/	
Contact with human body	Oral cavity	Oral cavity	/	
Prescription/over-the-counter use	Prescription	Prescription	/	
Method of use	Film forming	Film forming	/	
Curing mechanism	Be polymerized together with a resin cement.	Be polymerized together with a resin cement.		
Delivery form	Bottle	Bottle	/	
Physical Properties	The subject device and the predicate device have substantially equivalent physical properties as they all conform to Internal standard SOP of the company.		/	

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. 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 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 physical form, curing mechanism, 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 accelerated and 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 Appearance, Solid Content, Bond Strength (MPa), Whether there are traces left on the glass panel surface, Packing Amount Tolerance and Detection of Infrared Characteristic Peaks, 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.

The subject device is substantially equivalent to the predicate device that has been legally marketed for years 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. Through biocompatibility analysis, it can be concluded that the subject device is in compliance with the ISO 7405 and ISO 10993 standards.

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.