June 28, 2024

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

Re: K241204
Trade/Device Name: TopCEM-Veneer Light Cure Veneer Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA, EBF
Dated: April 30, 2024
Received: April 30, 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.

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,

FDA

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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)*

K241204

Device Name

TopCEM-Veneer Light Cure Veneer Cement

Indications for Use *(Describe)*

TopCEM-Veneer Light Cure Veneer Cement is used for permanent cementation of veneer made from materials of porcelain/ceramic and composites.

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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K241204

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:** May 23, 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-Veneer Light Cure Veneer Cement

Common name: Light Cure Veneer Cement

Classification name: Material, Tooth Shade, Resin (21 CFR 872.3690)

Regulatory Class: II

Product Code: EBF, EMA

4. **Predicate Device Information**

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Predicate
Ivoclar Vivadent AG	Variolink Esthetic LC	K142389	EBF	Primary
Rizhao HuGe Biomaterials Company, Ltd.	Dual Cure Resin Cement	K201790	EMA, EBF	Secondary

These predicate devices have not been subject to a design-related recall.

No reference device was used in this submission.

5. **Description of Device**

TopCEM-Veneer Light Cure Veneer Cement is a visible light curing cementation system that is designed for use with porcelain/ceramic and composite veneer restorations. The simple and versatile shade selections allow this material to be used with a wide range of veneer cases.

The principal organic components are mixtures of dental methacrylate resins (TEGDMA, EBP ADMA and UDMA). The inorganic filler loading is about 40% by volume having particle size range of about 0.01 to 5 microns.

Light Cure Veneer Cement is radiopaque, allowing for easy identification on radiographs. It is classified as Type 2 Class 2 Group 1 in accordance with ISO 4049:2019, which belongs to materials whose use requires the energy to be applied intro-orally.

6. Indications for Use

TopCEM-Veneer Light Cure Veneer Cement is used for permanent cementation of veneer made from materials of porcelain/ceramic and composites.

7. Summary of Physical and Chemical Properties Tests

The subject device belongs to Type 2 Class 2 Group 1 materials in accordance with ISO 4049. The physical properties of the subject device were determined and tested according to ISO 4049, ISO 29022 and FDA guidance “Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)]Submissions Document issued on: October 26, 2005”. Bench testings were performed on the subject device and the predicate devices, the test results demonstrated the substantial equivalence when compared to the predicate devices.

Summary of Physical and Chemical Properties Test		
Items per ISO 4049/ISO 29022	Pass/fail criteria	Conclusion
ISO 4049 5.2.2 Film thickness, luting materials	The film thickness of luting materials in any event shall be no greater than 50 μm.	Satisfactory
ISO 4049 5.2.7 Sensitivity to ambient light	When tested, the material shall remain physically homogeneous.	Satisfactory
ISO 4049 5.2.8 Depth of cure	The depth of cure of Class 2 restorative materials shall be no less than 1 mm if they are labelled by the manufacturer as opaque, or no less than 1.5 mm for other restorative materials.	Satisfactory
ISO 4049 5.2.9 Flexural strength	The flexural strength shall be equal to or greater than 50 MPa.	Satisfactory

ISO 4049 5.2.10 Water sorption and solubility	The water sorption shall be ≤ 40 μg/mm^3. The solubility of shall be ≤ 7.5 μg/mm^3.	Satisfactory
ISO 4049 5.5 Radio-opacity	The radio-opacity shall be equal to or greater than that of the same thickness of aluminium (1 mm of material).	Satisfactory
Shear bond strength (The test methods refer to the ISO 29022)	Meet internal standards.	Satisfactory
Bonding durability (The test methods refer to the ISO 29022)	Meet internal standards.	Satisfactory
Compressive strength Elastic modulus Surface hardness Filler particle size distribution Curing time	Meet internal standards.	Satisfactory

8. Technological Characteristics Comparison

All components of the subject device are based upon industry well-known chemistry. The curing mechanism of the subject device and predicate devices are polymerization of uncured methacrylate ester monomers. The subject device's reaction is caused by photo initiator. The following table shows the significant technological characteristics for the subject device and indicates the following similarities and differences with the predicate devices:

Technological Characteristics Comparison Table			
Technological Characteristics	Subject device	Primary predicate K142389	Secondary Predicate K201790
Monomer matrix	Methacrylate based	Methacrylate based	Methacrylate based
Physical Form	Paste	Paste	Paste
Indications of Use	Light Cure Veneer Cement is used for permanent cementation of veneer made from materials of porcelain/ceramic and composites.	Permanent adhesive luting of glass-ceramic, lithium disilicate glass-ceramic and composite restorations (inlays, onlays and veneers) Only use Variolink Esthetic LC for restorations with a low thickness of <2mm that have sufficient translucency (e.g. restorations made of IPS e.max R HT).	Dual Cure Resin Cement is a dental luting system designed 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, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations.
Prescription/over-the-counter use	Prescription	Prescription	Prescription
Delivery form	Packed in syringes	Packed in syringes	Packed in syringes

Technological Characteristics Comparison Table			
Technological Characteristics	Subject device	Primary predicate K142389	Secondary Predicate K201790
Radiographic Appearance	Radiopaque	Radiopaque	Radiopaque
Physical Properties	The subject device and the predicate devices have substantially equivalent physical properties as they all conform to ISO 4049, ISO 29022 and FDA guidance "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)]Submissions Document issued on: October 26, 2005".		

The indications of the subject device are all covered by that of the 510(k) cleared predicate devices. Based on the indications for use in 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.

Based on ISO 4049 Dentistry - Polymer-Based Restorative Materials, ISO 29022 Dentistry - Adhesive - Notched-edge sheer bond strength test and Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions, technological characteristics, physical properties, performance testing are carried to compare the subject device with predicate devices.

According to test results, the subject device has similar technological characteristics with the predicate devices.

9. Summary of Biocompatibility

The subject device is substantially equivalent to the predicate devices that have 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 devices.

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

Clinical test is not applicable.

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.