



December 22, 2023

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

Re: K233082
Trade/Device Name: TopCEM Dual Cure Resin Cement
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EMA
Dated: September 25, 2023
Received: September 26, 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 (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,



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

Indications for Use

Submission Number (if known)

K233082

Device Name

TopCEM Dual Cure Resin Cement

Indications for Use (Describe)

- Permanent cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers and other restorations made from materials of metals/alloys, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations.
- Permanent cementation for all types of root canal posts.
- Core build-ups.

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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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:** December 1, 2023

2. **Submitter Information:**

Owner's Name Rizhao HuGe Biomaterials Company, Ltd.
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Shandong Province, China 276800
Telephone 0086 633 2277268
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Contact Person Ms. Maggie Zheng
Contact Title Regulatory Affairs Manager
E-mail zhengxy@hugedent.com

3. **Device Name**

Trade name: TopCEM Dual Cure Resin Cement
Common name: Dual Cure Resin 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
COLTENE/WHALEDENT AG	PARAPOST PARACORE AUTOMIX 5ML	K052820	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 were used in this submission.

5. Description of Device

TopCEM Dual Cure Resin Cement is a versatile and ultimate dental dual cure (chemical and/or light cure) luting cement containing paste-paste of Base and Catalyst. The mixing ratio, based on volume, is 1 part base paste : 1 part catalyst paste. It is also a core build up material in syringes.

The principal organic components are mixtures of dental methacrylate resins (TEGDMA, EBPADMA and UDMA). The inorganic filler loading is about 40% by volume having particle size range of about 0.01 to 3 microns.

TopCEM Dual Cure Resin Cement is delivered in either two separated single syringes for Hand-mix or double-barrel syringes for Automix and comes in seven shades: TR (Translucent), A0 (Light+), A1 (Light), A2 (Medium), A3 (Dark), White (White Opaque) and Opaque (Universal Opaque).

TopCEM Dual Cure Resin Cement is radiopaque, allowing for easy identification on radiographs. It belongs to Type 2 Class 3 dual cure materials in accordance with ISO 4049. The curing mechanism of the predicate devices and subject device is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator and chemical polymerization initiator systems.

6. Indications for Use

- Permanent cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers and other restorations made from materials of metals/alloys, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations.
- Permanent cementation for all types of root canal posts.
- Core build-ups.

7. Summary of Physical and Chemical Properties Tests

The subject device belongs to Type 2 Class 3 dual cure 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 5.2.4 Working time, Class 1 and Class 3 luting materials	The material shall be capable of forming a thin layer; during its formation there shall be no detectable change in its homogeneity, shall be not less than 60 s.	Satisfactory
ISO 4049 5.2.6 Setting time, Class 3 materials	The setting time shall be not more than 10 min.	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 $\leq 40 \mu\text{g}/\text{mm}^3$.	Satisfactory
	The solubility of shall be $\leq 7.5 \mu\text{g}/\text{mm}^3$.	
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 Flexural strength Elastic modulus	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 all of polymerization of uncured methacrylate ester monomers. The reaction is caused by photo initiator and chemical polymerization initiator systems. 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 K233082	Primary predicate K052820	Secondary Predicate K201790
Monomer matrix	Methacrylate based	Methacrylate based	Methacrylate based

Technological Characteristics Comparison Table			
Technological Characteristics	Subject device K233082	Primary predicate K052820	Secondary Predicate K201790
Primary Filler(s)	Silanated Barium glass filler	Silanated Barium glass filler	Silanated Barium glass filler
Physical Form	Pastes of Catalyst and Base	Pastes of Catalyst and Base	Pastes of Catalyst and Base
Indications of Use	- Permanent cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers and other restorations made from materials of metals/alloys, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations. - Permanent cementation for all types of root canal posts. - Core build-ups.	ParaPost ParaCore automix 5ml is indicated for core build-ups and cementation of posts.	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
Curing method	Dual cure	Dual cure	Dual cure
Delivery form	Hand-mix / Automix	Automix	Hand-mix / Automix
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. The subject device has similar technological characteristics as the predicate devices. As compared to the primary predicate device, the subject device is also available in Hand-mix model, which is having the Catalyst and Base resin cement pastes packaged into physically separated single syringes instead of being packaged into a double barrel syringe as for the Automix. The base and catalyst are mixed in a 1:1 ratio to form dual-curing cement, and it will not pose any new issues of the safety and effectiveness. Therefore, the minor differences in the delivery system affect neither the intended use nor substantial equivalence.

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.