December 12, 2025

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

Re: K252785
Trade/Device Name: TopCEM Vigor SA Self-Adhesive Resin Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: November 10, 2025
Received: November 12, 2025

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252785

Please provide the device trade name(s).

TopCEM Vigor SA Self-Adhesive Resin Cement

Please provide your Indications for Use below.

-Cementation of all-ceramic, composite, and metal crowns, bridges, inlays, onlays, dental posts; 2-3-unite Maryland bridges and 3-unit inlay/onlay bridges (contraindicated for patients with bruxism or periodontitis).
-Cementation of fiber posts.
-Cementation of all-ceramic, composite, and metal restorations on implant abutments.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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 11, 2025

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 Vigor SA Self-Adhesive Resin Cement

Common name: Dental Cement

Classification name: Dental Cement (21 CFR 872.3275)

Regulatory Class: II

Product Code: EMA

4. **Predicate Device Information**

Owner/Operator	Device Trade Name	510 (k) No.	Product Code
3M ESPE AG	Malta	K100756	EMA

No reference device were used in this submission.

5. **Description of Device**

TopCEM Vigor SA Self-Adhesive Resin Cement is a dual-curing (chemical and/or light cure) luting cement containing paste-paste of Base and Catalyst. The cement contains inorganic fillers, and the inorganic filler loading is about 40% by volume having particle size range of

about 0.01 to 5 microns. The mixing ratio, based on volume, is 1 part base paste: 1 part catalyst paste.

TopCEM Vigor SA Self-Adhesive Resin Cement is delivered in double-barrel syringes.

TopCEM Vigor SA Self-Adhesive 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

- Cementation of all-ceramic, composite, and metal crowns, bridges, inlays, onlays, dental posts; 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (contraindicated for patients with bruxism or periodontitis).

- Cementation of fiber posts.

- Cementation of all-ceramic, composite, and metal restorations on implant abutments.

7. 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 device 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 device:

Technological Characteristics Comparison Table		
Technological Characteristics	Subject device K252785	Predicate device K100756
Composition of Materials	Methacrylate resins, phosphorylated methacrylate (MDP), silane treated glass powder, silane treated silica, pigments, initiator and stabilizer	Methacrylate resins, phosphorylated methacrylate (MDP), silane treated glass powder, silane treated silica, pigments, initiator and stabilizer
Physical Form	Pastes of Catalyst and Base	Pastes of Catalyst and Base
Indications of Use	● Cementation of all-ceramic, composite, and metal crowns, bridges, inlays,	● Final cementing of all-ceramic, composite, or metal inlays, onlays,

Technological Characteristics Comparison Table		
Technological Characteristics	Subject device K252785	Predicate device K100756
	onlays, dental posts; 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (contraindicated for patients with bruxism or periodontitis). ● Cementation of fiber posts. ● Cementation of all-ceramic, composite, and metal restorations on implant abutments.	crowns and bridges; 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis); ● Final cementing of posts and screws; ● Final cementation of all-ceramic, composite, or metal restorations on implant abutments.
Prescription/over-the-counter use	Prescription	Prescription
Curing method	Dual cure	Dual cure
Delivery form	Syringe	Syringe
Radiographic Appearance	Radiopaque	Radiopaque
Physical Properties	The subject device and the predicate device have substantially equivalent physical properties as they all conform to the ISO 4049, ISO 29022, ISO/TS 11405, and HUGE SOP.	

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 method, 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

The physical properties of the subject device, including Working time, Setting time, Film thickness, Flexural strength, Water sorption, Solubility, Compressive strength, Elastic modulus, Surface hardness, Shear bond strength, Bonding durability and Radio-opacity, were determined and tested according to ISO 4049, ISO 29022, ISO/TS 11405, and HUGE SOP, and the test results demonstrated the qualification and substantial equivalence when compared to the predicate device.

Additionally, the subject device is substantially equivalent to the predicate device that has been legally marketed already 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. Biocompatibility tests were performed fully following the ISO 7405 and ISO 10993 standards, and test results are sufficient to prove the safety of the subject device.

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.