December 20, 2024

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

Re: K242572
Trade/Device Name: TopCEM-Try in Veneer Try-in Gel
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: November 25, 2024
Received: November 25, 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

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)*

K242572

Device Name

TopCEM-Try in Veneer Try-in Gel

Indications for Use *(Describe)*

TopCEM-Try in Veneer Try-in Gel is used to evaluate the shade and the matching of the restoration prior to permanent cementation.

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.

K242572 - 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 16, 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
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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-Try in Veneer Try-in Gel

Common name: Veneer Try-in Gel

Classification name: Material, Tooth Shade, Resin

Regulation Number: 21 CFR 872.3690

Regulatory Class: II

Product Code: EBF

4. **Predicate Device Information**

Owner/Operator	Predicate Device Trade Name	510 (k) No.	Product Code	Classification Name	Regulation Number	Predicate
Ivoclar Vivadent AG	Variolink Esthetic Try-In	K142389	EBF	Material, Tooth Shade, Resin	872.3690	Primary
3M Company	3M RelyX Veneer Cement Try-in Paster	K002452	EMA	Cement, Dental	872.3275	Reference

5. Description of Device

TopCEM-Try in Veneer Try-in Gel is primarily made of polyethylene glycol, inorganic fillers and pigments. It is used to indicate the color of the Light Cure Veneer Cement before use, so as to select the right color to achieve the best aesthetic effect. The polyethylene glycol and inorganic filler in the Veneer Try-in Gel component are hydrophilic and can be rinsed off with a water gun nozzle after the color test operation.

The principal organic components of TopCEM-Try in Veneer Try-in Gel are mixtures of polyethylene glycol, and the inorganic fillers loading is about 50% by volume.

6. Indications for Use

TopCEM-Try in Veneer Try-in Gel is used to evaluate the shade and the matching of the restoration prior to permanent cementation.

7. Summary of Physical and Chemical Properties Tests

The physical properties of the subject device were determined and tested according to HuGe internal inspection standard. Bench testing was performed on the subject device and the primary predicate device, the test results demonstrated the substantial equivalence when compared to the primary predicate device.

Summary of Physical and Chemical Properties Test		
Items per internal standards	Pass/fail criteria	Conclusion
Appearance	Meet internal standards.	Satisfactory
Shade	Meet internal standards.	Satisfactory
Liquidity	Meet internal standards.	Satisfactory
Consistence	Meet internal standards.	Satisfactory

8. Technological Characteristics Comparison

All components of the subject device are based upon industry well-known chemistry. 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 TopCEM-Try in Veneer Try-in Gel (K242572)	Primary predicate device Variolink Esthetic Try-in (K142389)	Reference predicate device 3M RelyX Veneer Cement Try-in Paster (K002452)
Main components	TopCEM-Try in Veneer try-in gel is primarily made of polyethylene glycol, colorant, inorganic fillers and pigments.	The Variolink Esthetic Try-In pastes contain glycerine, mineral fillers and inorganic fillers.	RelyX Try-In paste contains polyethylene glycol (PEG), zirconia/silica filler and pigments.
Physical Form	Paste	Paste	/
Water solubility	Hydrophilic	Hydrophilic	/
Indications of Use	TopCEM-Try in Veneer Try-in Gel is used to evaluate the shade and the matching of the restoration prior to permanent cementation.	To evaluate the overall effect of the restoration in conjunction with the various Variolink Esthetic shades prior to permanent cementation.	/
Prescription/over-the-counter use	Prescription	Prescription	/
Delivery form	Packed in syringe	Packed in syringe	/
Storage Condition	Store TopCEM-Try in Veneer Try-in Gel at 2-25 °C and away from direct light.	Storage temperature: 2-28 °C / 36-82 °F.	/
Physical Properties	The subject and the primary predicate device have substantially equivalent physical properties as they all conform to HuGe internal inspection standard.		/

The indications of the subject device are similar to that of 510(k) cleared primary predicate device. Based on the indications for use in comparison to primary predicate device, the subject device has demonstrated substantial equivalence to the predicate device.

Based on HuGe internal inspection standard, technological characteristics, physical properties, performance testing are carried to compare the subject device with primary predicate device. According to test results, the subject device has similar technological characteristics with the primary predicate device.

9. Summary of Biocompatibility

The subject device is substantially equivalent to the predicate devices. 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 and the FDA guidance titled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'" The test endpoint studies include cytotoxicity, sensitization, and irritation.

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 demonstrated substantial equivalence. The minor differences in indications for use between the subject and predicate device does not affect the general intended use or substantial equivalence. Rizhao HuGe Biomaterials Company, Ltd. concludes that the subject device is substantially equivalent to the predicate devices described herein.