October 6, 2021

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

Re: K202063/S002
Trade/Device Name: TrusFIL Universal Composite Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: July 28, 2021
Received: August 9, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202063

Device Name
TrusFIL Universal Composite Restorative

Indications for Use *(Describe)*
TrusFIL Universal Composite Restorative is a visible light curing dental restorative material indicated for:
- Direct anterior and posterior restorations (including occlusal surfaces);
- Core Build-ups;
- Splinting;
- Indirect restorations including inlays, onlays and veneers.

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-k202063

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:** September 29, 2021

2. **Submitter Information:**

Owner's Name	Rizhao HuGe Biomaterials Company, Ltd.
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Contact Person	Mrs. Maggie Zheng
Contact Title	Regulatory Affairs Manager
E-mail	zhengxy@hugedent.com

3. **Device Name**

Trade name: TrusFIL Universal Composite Restorative

Common name: Universal Composite Restorative

Classification name: Material, Tooth Shade, Resin

Regulatory Class: II

Product Code: EBF

4. **Predicate Device Information**

Table 1: Predicate Device Information

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Predicate
3M ESPE Dental Products	Filtek Supreme Ultra Universal Restorative	K083610	EBF	Primary

This predicate device has not been subject to a design-related recall.

No reference devices were used in this submission.

5. Description of Device

TrusFIL Universal Composite Restorative is a visible-light activated, restorative composite designed for use in anterior and posterior restorations.The principal organic components are mixtures of dental methacrylate resins (Bis-GMA, TEGDMA, EBPADMA). The inorganic filler loading is about 54% by volume having particle size range of about 0.01 to 2 microns. It is packaged in syringes and single-dose capsules. Single-dose delivery is intended for single patient (single use) only to prevent cross-contamination between patients.

Available shades include opaque dentin shades, regular body shades and enamel shades. All shades are radiopaque.

6. Indications for Use

TrusFIL Universal Composite Restorative is a visible light curing dental restorative material indicated for:

- Direct anterior and posterior restorations (including occlusal surfaces);
- Core Build-ups;
- Splinting;
- Indirect restorations including inlays, onlays and veneers.

7. Summary of Physical Properties Tests

TrusFIL Universal Composite Restorative is classified as Type 1 Class 2 and both Group 1 and Group 2 in accordance with ISO 4049: 2009. The physical properties were determined and tested according to ISO 4049: 2009 and FDA guidance “Guidance for Industry and FDA Staff Dental Composite Resin Devices -Premarket Notification [510(k)]Submissions Document issued on: October 26, 2005”.

In-vitro bench tests were performed on the TrusFIL Universal Composite Restorative including the items listed in the table 4 below. The test results indicated that the TrusFIL Universal Composite Restorative meets the pass/fail criteria and supports substantial equivalence when compared to the predicate device on physical properties.

Table 4: Summary of Physical Properties Test		
Items	Pass/fail criteria	Conclusion
ISO 4049: 2009 5.2.7 Sensitivity to ambient light, Class 2 materials	The material shall remain physically homogeneous.	Meet the criteria per ISO 4049
ISO 4049: 2009 5.2.8 Depth of cure, Class 2 materials	Opaque restorative materials: ≥1 mm Other restorative materials: ≥1.5 mm	Meet the criteria per ISO 4049
ISO 4049: 2009 5.2.9 Flexural strength	The flexural strength shall be equal to or greater than 100 MPa.	Meet the criteria per ISO 4049
ISO 4049: 2009 5.2.10 Water sorption and solubility	a) The water sorption shall be ≤ 40 μg/mm^3. b) The solubility shall be shall be ≤ 7.5 μg/mm^3.	Meet the criteria per ISO 4049
ISO 4049: 2009 5.3 Shade, restorative materials	The shade of the set material shall match closely that of the manufacturer's shade guide. The set material shall be evenly pigmented when viewed without magnification.	Meet the criteria per ISO 4049
ISO 4049: 2009 5.4 Colour stability after irradiation and water sorption	No more than a slight change in colour shall be observed.	Meet the criteria per ISO 4049
ISO 4049: 2009 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).	Meet the criteria per ISO 4049
FDA guidance Elastic modulus	The elastic modulus shall be equal to or greater than 2 GPa.	Meet the criteria per internal standard
FDA guidance Surface hardness	The surface hardness shall be equal to or greater than 30HV.	Meet the criteria per internal standard
FDA guidance Compressive strength	The compressive strength shall be equal to or greater than 200 MPa.	Meet the criteria per internal standard

8. Technological Characteristics

The following table shows the significant technological characteristics and indicates the similarities and differences with the predicate device:

Table 5: Technological Characteristics Comparison Table		
Technological Characteristics	Subject device	Primary predicate device
	TrusFIL Universal Composite Restorative (K202063)	Filtek Supreme Ultra Universal Restorative(K083610)
Composition of Materials	Methacrylate-based resins, photo initiator, fillers and pigments.	Methacrylate-based resins, photo initiator, fillers and pigments.
Physical Form	Paste	Paste
Indications of Use	TrusFILUniversal Composite Restorative is a visible light curing dental restorative material indicated for: - Direct anterior and posterior restorations (including occlusal surfaces); - Core Build-ups; - Splinting; - Indirect restorations including inlays, onlays and veneers.	Filtek Supreme Ultra universal restorative is indicated for use in: • Direct anterior and posterior restorations (including occlusal surfaces) • Core Build-ups • Splinting • Indirect restorations including inlays, onlays and veneers
Prescription/over-the-counter use	Prescription	Prescription
Curing method	Light cure	Light cure
Delivery form	Syringe and single-dose capsule	Syringe and single-dose capsule
Radio-opacity	Meet the criteria per ISO 4049	Meet the criteria per ISO 4049
Physical Properties	The subject device and the predicate device have substantially equivalent physical properties as they all meet the criteria per ISO 4049 and conform to FDA guidance “Guidance for Industry and FDA Staff Dental Composite Resin Devices -Premarket Notification [510(k)]Submissions Document issued on: October 26, 2005”.	
FDA-Recognized Standards	ISO 4049; ISO 7405; ISO 10993-1	ISO 4049; ISO 7405; ISO 10993-1

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, Filtek Supreme Ultra Universal Restorative (K083610). 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 primary predicate device have minor

different Indications for Use language in the first indication. However, the difference does not change the intended use or substantial equivalence, both products are intended for direct anterior and posterior restorations. Besides, other comparison items such as description of material, physical form, curing method, delivery form and physical properties, etc. are the same or very similar. And both products are supplied for prescription use.

9. Summary of Biocompatibility

The subject device, TrusFIL Universal Composite Restorative, is substantially equivalent to the predicate device that have been legally marketed for decades and with no clinical adverse events. The formulation of the subject device does not contain any non-conventional chemicals compared to the legally marketed predicate device.

Biocompatibility evaluation and tests were performed according to ISO 10993-1, ISO 7405 and FDA guidance "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process Document issued on: September 4, 2020". Biocompatibility tests include Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Subchronic Toxicity, Genotoxicity and Pulp and Dentine Usage. TrusFIL Universal Composite Restorative has been demonstrated as biocompatible for its intended use.

10. Clinical Performance Data

Not applicable. Clinical performance testing has not been performed for the subject device.

11. Risk Analysis

The risk analysis of TrusFIL Universal Composite Restorative was conducted according to ISO 14971. As analyzed, the residual risk of the TrusFIL Universal Composite Restorative is considered acceptable. The benefits of the product are considered to outweigh the risks outlined in the risk analysis.

12. Conclusions

Based on the indications for use, technological characteristics, performance testing and comparison to predicate device, 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 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.

13. Photo of the device