October 12, 2022

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: K221510
Trade/Device Name: TrusFIL-Flow Flowable Composite Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: July 6, 2022
Received: July 14, 2022

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)*
K221510

Device Name
TrusFIL-Flow Flowable Composite Restorative

Indications for Use *(Describe)*
TrusFIL-Flow Flowable Composite Restorative is a visible light curing dental restorative material indicated for:
- Class III and V restorations
- Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations)
- Base/liner under direct restorations
- Repair of small defects in indirect restorations
- Pit and fissure sealant
- Undercut blockout
- Repair of resin and acrylic temporary materials

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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005_510 (k) Summary
K221510

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:** Oct. 11, 2022

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
Contact Person	Ms. Maggie Zheng
Contact Title	Regulatory Affairs Manager
E-mail	zhengxy@hugedent.com

3. **Device Name**

Trade name: TrusFIL-Flow Flowable Composite Restorative

Common name: Flowable Composite Restorative

Classification name: Material, Tooth Shade, Resin

Regulatory Class: II

Product Code: EBF

4. **Predicate Device Information**

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Predicate
3M ESPE Dental Products	FILTEK SUPREME ULTRA FLOWABLE RESTORATIVE	K100235	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-Flow Flowable Composite Restorative is a visible light curing dental restorative material intended to restore carious lesions or structural defects in teeth in combination of a bonding agent and with or without other materials such as luting, etching agents, cavity liners, universal composites and others commonly used in a tooth restoration. The principal organic components are mixtures of dental methacrylate resins (Bis-GMA, TEGDMA, EBPADMA). The inorganic filler loading is about 46% by volume having particle size range of about 0.01 to 3 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 and regular body shades. All shades are radiopaque.

6. Indications for Use

TrusFIL-Flow Flowable Composite Restorative is a visible light curing dental restorative material indicated for:

- Class III and V restorations
- Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations)
- Base/liner under direct restorations
- Repair of small defects in indirect restorations
- Pit and fissure sealant
- Undercut blockout
- Repair of resin and acrylic temporary materials

7. Summary of Physical Properties Tests

TrusFIL-Flow Flowable Composite Restorative is classified as Type 1 Class 2 Group 1 in accordance with ISO 4049: 2019. The physical properties were determined and tested according to ISO 4049: 2019 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-Flow Flowable Composite Restorative including the items listed in the table below. The test results indicated that the TrusFIL-Flow Flowable Composite Restorative meets the pass/fail criteria and supports substantial equivalence when compared to the predicate device on physical properties.

Items	Pass/fail criteria	Conclusion
ISO 4049: 2019 5.2.7 Sensitivity to ambient light, Class 2 materials	The material shall remain physically homogeneous.	Meet the criteria per ISO 4049
ISO 4049: 2019 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: 2019 5.2.9 Flexural strength	The flexural strength shall be equal to or greater than 80 MPa.	Meet the criteria per ISO 4049
ISO 4049: 2019 5.2.10 Water sorption and solubility	a) The water sorption shall be ≤ 40 $\mu g/mm^3$. b) The solubility shall be shall be ≤ 7.5 $\mu g/mm^3$.	Meet the criteria per ISO 4049
ISO 4049: 2019 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: 2019 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: 2019 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

Items	Pass/fail criteria	Conclusion
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:

Technological Characteristics	Subject device	Primary predicate device
	TrusFIL-Flow Flowable Composite Restorative(K221510)	Filtek Supreme Ultra Flowable Restorative(K100235)
Composition of Materials	Methacrylate-based resins, photo initiator, fillers and pigments	Methacrylate-based resins, photo initiator, fillers and pigments
Physical Form	Flowable Paste	Flowable Paste
Indications of Use	TrusFIL-Flow Flowable Composite Restorative is a visible light curing dental restorative material indicated for: - Class III and V restorations - Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations) - Base/liner under direct restorations - Repair of small defects in indirect restorations - Pit and fissure sealant - Undercut blockout - Repair of resin and acrylic temporary materials	Filtek Supreme Flow restorative is indicated for use in: - Class III and V restorations -Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations) -Base/liner under direct restorations - Repair of small defects in indirect restorations - Pit and fissure sealant - Undercut blockout -Repair of resin and acrylic temporary materials
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”.	

Technological Characteristics	Subject device	Primary predicate device
	TrusFIL-Flow Flowable Composite Restorative(K221510)	Filtek Supreme Ultra Flowable Restorative(K100235)
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(K221510) are very similar to those of the predicate device, Filtek Supreme Ultra Flowable Restorative(K100235). 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 in language. 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-Flow Flowable 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 tests were performed fully following the ISO 10993 standards. The test items include Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Subchronic Toxicity, Genotoxicity and Pulp and Dentine Usage.

10. Clinical Performance Data

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

11. Risk Analysis

The risk analysis of TrusFIL-Flow Flowable Composite Restorative was conducted according to ISO 14971. As analyzed, the residual risk of the TrusFIL-Flow Flowable 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 as safe and as effective as the predicate device 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.