



June 23, 2025

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

Re: K251271

Trade/Device Name: TempFIT Temporary Crown and Bridge Resin
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: April 24, 2025
Received: April 24, 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.

K251271

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Please provide the device trade name(s).

?

TempFIT Temporary Crown and Bridge Resin

Please provide your Indications for Use below.

?

The product is a self-curing composite for the fabrication of temporary crowns, bridges, inlays, onlays and veneers.

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)

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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: June 12, 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
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Contact Person	Ms. Maggie Zheng
Contact Title	Regulatory Affairs Manager
E-mail	zhengxy@hugedent.com

3. Device Name

Trade name: TempFIT Temporary Crown and Bridge Resin
Common name: Temporary Crown and Bridge Resin
Classification name: Material, Tooth Shade, Resin (21 CFR 872.3770)
Regulatory Class: II
Product Code: EBG

4. Predicate Device Information

Owner/Operator	Device Trade Name	510 (k) No.	Product Code
DMG USA, INC.	Luxatemp Ultra/Star	K101710	EBG

No reference device was used in this submission.

5. Description of Device

TempFIT Temporary Crown and Bridge Resin is a self-curing composite for the fabrication of temporary crowns, bridges, inlays, onlays and veneers. The mixing ratio, based on volume, base paste: catalyst paste =1:1 or 10:1.

TempFIT Temporary Crown and Bridge Resin is delivered in a bio-cartridge.

The curing mechanism between methacrylates is self-curing, which fundamentally belongs to free radical polymerization in reaction principle. Free radical polymerization typically occurs in unsaturated molecules containing double bonds. Both methacrylate resins in TempFIT Temporary Crown and Bridge Resin and silane coupling agents on filler surfaces contain numerous carbon-carbon unsaturated double bonds. When the two-component system is mixed, a redox reaction generates abundant free radicals that initiate the polymerization of these double bonds.

6. Indications for Use

The product is a self-curing composite for the fabrication of temporary crowns, bridges, inlays, onlays and veneers.

7. Technological Characteristics Comparison

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 (TempFIT Temporary Crown and Bridge Resin)	Predicate device K101710
Composition of Materials	The product is temporary crown and bridge materials composed of double pastes of Base and Catalyst, based on methacrylic resin, with a certain amount of inorganic fillers and additives.	The product is temporary crown and bridge materials composed of double pastes of Base and Catalyst, based on methacrylic resin, with a certain amount of inorganic fillers and additives.
Physical Form	Pastes of Catalyst and Base	Pastes of Catalyst and Base
Indications of Use	The product is a self-curing composite for the fabrication of temporary crowns, bridges, inlays, onlays and veneers.	Luxatemp Ultra/Star is a self-curing or dual-curing composite for the fabrication of temporary crowns and bridges, inlays, onlays and veneers.
Clinical condition	Dental restorations	Dental restorations
Contact with human body	Oral cavity	Oral cavity
Prescription/over-the-counter use	Prescription	Prescription
Curing method	Self-curing	Self-curing

Technological Characteristics Comparison Table			
Technological Characteristics		Subject device (TempFIT Temporary Crown and Bridge Resin)	Predicate device K101710
Delivery form		Cartridge	Cartridge
Physical Properties	Appearance	Visual inspection shows that there is no foreign impurities in the paste.	Visual inspection shows that there is no foreign impurities in the paste.
	Colour	The colours of the material show no more than a slight difference with the colour indicated by the manufacturer.	The colours of the material show no more than a slight difference with the colour indicated by the manufacturer.
	Working time	≥50s	≥50s
	Setting time	≤10min	≤10min
	Surface finish	A test specimen polished has a glossy surface.	A test specimen polished has a glossy surface.
	Flexural strength	≥50MPa	≥50MPa
	Water sorption	≤40µm/mm ³	≤40µm/mm ³
	Solubility	≤7.5µm/mm ³	≤7.5µm/mm ³
	The subject device and the predicate device have substantially equivalent physical properties as they all conform to the ISO 10477 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 Appearance, Colour, Working time, Setting time, Surface finish, Flexural strength, Water sorption and Solubility, were determined and tested according to ISO 10477 and Internal standard SOP of the company, 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.