September 29, 2020

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

Re: K201790
Trade/Device Name: Dual Cure Resin Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA, EBF
Dated: July 17, 2020
Received: July 27, 2020

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)*
K201790

Device Name
Dual Cure Resin Cement

Indications for Use *(Describe)*
Dual Cure Resin Cement is a dental luting system designed for cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers, dental posts and other restorations made from materials of metals/alloys, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations.

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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K201790

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:** September 29, 2020

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: Dual Cure Resin Cement

Common name: Dual Cure Resin Cement

Classification name: Dental Cement (21 CFR 872.3275)

Regulatory Class: II

Product Code: EMA, EBF

4. **Predicate Device Information**

Table 1: Predicate Device Information

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Predicate
IVOCLAR VIVADENT AG	Multilink Automix	K123397	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**

Dual Cure Resin Cement is a versatile and ultimate dental dual cure (chemical and/or light cure) luting cement. This multi-purpose device is designed for cementation of all sorts of dental restorations made from materials of metals/alloys, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations.

Dual Cure Resin Cement contains paste-paste of Base and Catalyst comprising primarily of dental methacrylate resins and inorganic fillers (with particle size range from about 0.01 - 3 microns and a filler volume of about 40%), inorganic pigments, photo-initiation and chemical curing systems. The mixing ratio, based on volume, is 1 part base paste : 1 part catalyst paste.

Dual Cure Resin Cement is delivered in either two seperated single syringe for Hand-mix and double-barrel syringes for Automix and comes in seven shades: TR (Translucent), A0 (Light+), A1 (Light), A2 (Medium), A3 (Dark), White (White Opaque) and Opaque (Universal Opaque).

Dual Cure Resin Cement is radiopaque, allowing for easy identification on radiographs.

6. Indications for Use

Dual Cure Resin Cement is a dental luting system designed for cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers, dental posts and other restorations made from materials of metals/alloys, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations.

7. Summary of Physical and Chemical Properties Tests

Dual Cure Resin Cement is classified as Type 2 Class 3 in accordance with ISO 4049, which belongs to luting materials that are cured by the application of external energy and also have a self-curing mechanism present (“dual cure” materials).

Test standards and methods based on ISO 4049:2009 and ISO 29022:2013:

ISO 4049: 2009 Dentistry - Polymer-Based Restorative Materials
ISO 29022:2013 Dentistry - Adhesive - Notched-edge sheer bond strength test

Table 4: Summary of Physical and Chemical Properties Test

Items per ISO 4049: 2009/ ISO 29022:2013	Pass/fail criteria	Conclusion
ISO 4049: 2009 5.2.2 Film thickness, luting materials	The film thickness of luting materials in any event shall be no greater than 50 μm.	Satisfactory

ISO 4049: 2009 5.2.4 Working time, Class 1 and Class 3 luting materials	The material shall be capable of forming a thin layer; during its formation there shall be no detectable change in its homogeneity, shall be not less than 60 s.	Satisfactory
ISO 4049: 2009 5.2.6 Setting time, Class 3 materials	The setting time shall be not more than 10 min.	Satisfactory
ISO 4049: 2009 5.2.9 Flexural strength	The flexural strength shall be equal to or greater than 50 MPa.	Satisfactory
ISO 4049: 2009 5.2.10 Water sorption and solubility	The water sorption shall be ≤ 40 μg/mm^3. The solubility of shall be ≤ 7.5 μg/mm^3.	Satisfactory
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).	Satisfactory
Shear bond strength (The test method equal to the ISO 29022:2013)	Shear bond strength for enamel and dentin≥8 MPa (Internal standard)	Satisfactory

8. Technological Characteristics

All components of the subject device are based upon industry well-known chemistry. The curing mechanism of the subject device and predicate devices 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 devices:

Table 5: Technological Characteristics Comparison Table

Technological Characteristics	Subject device (Dual Cure Resin Cement)	Primary predicate K123397
Monomer matrix	Methacrylate based	Methacrylate based
Primary Filler(s)	Silanated Barium glass filler	Silanated Barium glass filler
Physical Form	Pastes of Catalyst and Base	Pastes of Catalyst and Base
Indications of Use	Dual Cure Resin Cement is a dental luting system designed for cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers, dental posts and other restorations made from materials of metals/alloys, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations.	Multilink Automix is used for the permanent cementation of indirect restorations where a strong bond us desired: - Inlays, onlays, crowns, bridges and root posts made of: ● Metal and metal ceramics ● All-ceramics, in particular opaque zirconium oxide ceramics ● Composites and fiber-reinforced composites
Prescription/over-the-counter use	Prescription	Prescription

Table 5: Technological Characteristics Comparison Table		
Technological Characteristics	Subject device (Dual Cure Resin Cement)	Primary predicate K123397
Curing method	Dual cure	Dual cure
Delivery form	Hand-mix / Automix	Automix
Radiographic Appearance	Radiopaque	Radiopaque
Physical Properties	The subject device and the predicate devices have substantially equivalent physical properties as they all conform to the specifications set by ISO 4049 and ISO 29022.	

The subject device has the same technological characteristics as the predicate devices with the exception of the additional hand-mixing option. As compared to the predicated devices, the subject device is also available in Hand-mix, which is having the Catalyst and Base resin cement pastes packaged into physically separated single syringes instead of being packaged into a double barrel syringe as for the Automix. Regardless of which mode of operation by Hand-mix or Automix, the base and catalyst are mixed in a 1:1 ratio to form dual-curing cement, and it will not pose any new issues of the safety and effectiveness. Therefore, the minor differences in the delivery system affect neither the intended use nor substantial equivalence.

9. Summary of Biocompatibility

The new device, Dual Cure Resin Cement, is substantially equivalent to the predicate devices that have been legally marketed for decades and with no clinical adverse events. The formulation of new device does not contain any non-conventional chemicals compared to the legally marketed predicate device.

We selected our Dual Cure Resin Cement [Hand-mix, shade: Opaque (Universal Opaque)] as the representative model in biocompatibility tests because it is the worst case scenario. In addition, the Hand-mix and Automix of our Dual Cure Resin Cement have the same chemical compositions, raw material suppliers, curing method and other technological characteristic.

Biocompatibility tests were performed fully following the ISO 10993 standards. The test items include Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Subchronic Toxicity and Genotoxicity.

10. Clinical Performance Data

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

11. Conclusions

Based on the indications for use, technological characteristics, performance testing and

comparison to predicate devices, 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 devices 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 devices described herein.