December 5, 2024

Liaoning Rachcera Material Technology Co.,Ltd.
Liang Chen
General Manager
NO.31-1-5, Chang Qingnan Street, Hunnan New District
Shenyang, Liaoning 110000
China

Re: K242740
Trade/Device Name: Dental Lithium Disilicate Glass Ceramic (HT, ML-HT, LT, ML-LT, MT, MO, HO)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: September 11, 2024
Received: September 11, 2024

Dear Liang Chen:

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,

Bobak Shirmohammadi -S

For 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K242740

Device Name

Dental Lithium Disilicate Glass Ceramic (HT, ML-HT, LT, ML-LT, MO, HO)

Indications for Use *(Describe)*

Dental Lithium Disilicate Glass Ceramic is available using CAD/CAM and hot pressing techniques for the preparation of full ceramic crowns, inlays, onlays, veneer and full ceramic 3-unit anterior bridges.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 4 - 510(k) Summary K242740

1. Submitter's Identifications

Submitter's Name: Liaoning Rachcera Material Technology Co.,Ltd.
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2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
Address: Room 304, Building A, No. 62 Nanyun 2nd Road, Science Town, Huangpu District, Guangzhou City, Guangdong, 510663, China
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Contact Title: Regulation Control Manager
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3. Name of the Device

Device Classification Name: Powder, Porcelain
Regulation Description: Porcelain powder for clinical use
Trade Name: Dental Lithium Disilicate Glass Ceramic
Model: HT, ML-HT, LT, ML-LT, MT, MO, HO
Regulation Medical Specialty: Dental
Review Panel: Dental
Product Code: EIH
Regulation Number: 21 CFR 872.6660
Device Classification: Class II

4. The Predicate Devices

Predicate device: K230487 Dental Lithium Disilicate Glass-Ceramic Fuzhou Rick Brown Biomaterials Co., Ltd.

5. Device Description

Dental Lithium Disilicate Glass-Ceramic is a lithium disilicate ceramic to be supplied

in the form of cuboid and cylinder. Dental Lithium Disilicate Glass-Ceramic can be fabricated using CAD/CAM and hot pressing technologies. The device is a glass type material used for aesthetic purposes of full ceramic crowns, inlays, onlays, veneer and full ceramic 3unit anterior bridges.

The ceramics material is composed of SiO_2, Li_2O, K_2O, P_2O_5, Al_2O_3, ZrO_2 and other oxides. It contains inorganic pigments. The inorganic pigments generate the color on the restorations, after sintering at dental labs, that matches natural color of patient's teeth. The performance of the device conforms to ISO 6872:2015 Dentistry: Ceramic Materials. It is a single-use device, and provided non-sterile.

6. Indications for Use

Dental Lithium Disilicate Glass Ceramic is available using CAD/CAM and hot pressing techniques for the preparation of full ceramic crowns, inlays, onlays, veneer and full ceramic 3-unit anterior bridges.

7. Summary of Substantial Equivalence

Table 1 Comparison to Predicate Device

	Proposed Device	**Predicate device**	**Comparison**
510k Number	K242740	K230487	------
Product Code	EIH	EIH	Same
Regulation No.	21 CFR 872.6660	21 CFR 872.6660	Same
Class	2	2	Same
Proprietary Name	Dental Lithium Disilicate Glass Ceramic	Dental Lithium Disilicate Glass-Ceramic	------
Model:	HT, ML-HT, LT, ML-LT, MT, MO, HO	------	------
Manufacturer	Liaoning Rachcera Material Technology Co.,Ltd.	Fuzhou Rick Brown Biomaterials Co., Ltd.	------
Indications for Use	Dental Lithium Disilicate Glass Ceramic is available using CAD/CAM and hot pressing techniques for the preparation of full ceramic	Dental Lithium Disilicate Glass-Ceramic is available using CAD/CAM and hot pressing techniques for the preparation of	Same

	crowns, inlays, onlays, veneer and full ceramic 3-unit anterior bridges.	full ceramic crowns, inlays, onlays, veneer and full ceramic 3-unit anterior bridges.	
Materials	SiO_2, Li_2O, K_2O, P_2O_5, Al_2O_3, ZrO_2 and other oxides.	SiO_2, Li_2O, K_2O, P_2O_5, Al_2O_3, ZrO_2 and other oxides.	Same
Environment of use	Prescription Use	Prescription Use	Same
Design	Cuboid, Cylinder	Cuboid, Cylinder	Same
Color	Translucency: High Translucency (HT) Medium translucency (MT) Low Translucency (LT) Medium Opacity (MO) High Opacity (HO) Shades: HT/MT/LT:16 A-D and 4 Bleach MO:5MO 0 – MO 4 HO:3HO 0 – HO2	Translucency: High Translucency (HT) Medium translucency (MT) Low Translucency (LT) Medium Opacity (MO) High Opacity (HO) Shades: HT/MT/LT:16 A-D and 4 Bleach MO:5MO0 – MO 4 HO:3HO0 – HO2	Same
Crystallization State as Supplied	Cuboid: Partially crystallized, final crystallization done by dental laboratory Cylinder: Fully crystallized	Cuboid: Partially crystallized, final crystallization done by dental laboratory Cylinder: Fully crystallized	Same
Sterile	Non-sterile	Non-sterile	Same
Single Use	Yes	Yes	Same
Types, Class (ISO 6872:2015)	Type II, Class 3	Type II, Class 3	Same
Freedom from Extraneous materials	Free from extraneous materials	Free from extraneous materials	Same

Flexural Strength	≥300MPa	≥300MPa	Same
Linear thermal Expansion coefficient	$(9.8\pm0.5)\times10^{-6}K^{-1}$	$(9.8\pm0.5)\times10^{-6}K^{-1}$	Same
Glass Transition Temperature	495±20℃	495±20℃	Same
Chemical Solubility	< 100 μ g/ cm^2	< 100 μ g/ cm^2	Same
Shrinkage factor	Length: 1.0011 Width: 1.0018 Height: 1.0036	Length: 1.0011 Width: 1.0018 Height: 1.0036	Same
Radioactivity	Meets ISO 6872 requirements ≤ 1.0 Bq/g of 238U	Meets ISO 6872 requirements ≤ 1.0 Bq/g of 238U	Same
Biocompatibility	Conform to ISO 7405:2018	Conform to ISO 7405:2018	Same
Discussion for Substantially Equivalent (SE)	The proposed device has same indications for use as the predicate device. The proposed device is similar to the predicate device in terms of design.		

8. Summary of Non-Clinical Testing

Bench tests were conducted to verify that the proposed device met all requirements. The test results demonstrated that the proposed device complies with the following standards:

- ISO 6872 Fourth edition 2015-06-01, Dentistry - Ceramic materials,
- ISO 7405 Third edition 2018-10 Corrected version 2018-12, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry,
- ISO 10993-3 Third edition 2014-10-1, Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity,
- ISO 10993-5 Third edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity,
- ISO 10993-6 Third edition 2016-12-01, Biological evaluation of the medical devices - Part 6: Tests for Local Effects after Implantation,
- ISO 10993-10 Fourth edition 2021-11, Biological evaluation of medical devices - Part 10: Tests for skin sensitization,
- ISO 10993-11 Third edition 2017-09, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity,
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that subject device Dental Lithium Disilicate Glass Ceramic is as safe and effective as the predicate device. Dental Lithium Disilicate Glass Ceramic is substantial equivalent to the legally marketed predicate device K230487 Dental Lithium Disilicate Glass-Ceramic.