July 3, 2023

Fuzhou Rick Brown Biomaterials Co., Ltd.
% Sherry Kang
Registrar
Shenzhen Huatongwei International Inspection Co., Ltd.
1/F, Bldg 5, Hongfa Hi-tech Industrial Park
Tianliao, Guangming
Shenzhen, Guangdong 518107
China

Re: K230487
Trade/Device Name: Dental Lithium Disilicate Glass-Ceramic
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 4, 2023
Received: April 4, 2023

Dear Sherry Kang:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., 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.

510(k) Number *(if known)*

K230487

Device Name
Dental Lithium Disilicate Glass-Ceramic

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.

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Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	**K230487**
Date:	February 14th, 2023
Type of 510(k) Submission:	Traditional 510(k)
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Fuzhou Rick Brown Biomaterials CO., LTD. The first and second floors of R&D Building, Jiecheng Industrial Park, No.36 Houshan Zhaishan, Nanyu Town, High-Tech District, Fuzhou, Fujian Province, China Tel: +86-0591-23507151 E-mail: sheshuiyu@brownmaterial.com
Contactor:	Sherry Kang Shenzhen Huatongwei International Inspection Co.,Ltd. 1/F, Bldg5, Hongfa Hi-tech Industrial Park, Tianlia, Guangming, Shenzhen, Guangdong, 518107 China E-mail: MDconsult@szhtw.com.cn Tel: 86-400-963-0755

2. Device Description

Proprietary Name:	Dental Lithium Disilicate Glass-Ceramic
Classification Name:	Powder, Porcelain
Product Code:	EIH
Device Class:	2
Regulation Number:	21 CFR 872.6660
Review Panel:	Dental
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.
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 3-unit anterior bridges. The ceramics material is composed of SiO_2, Li_2O, K_2O, Al_2O_3, P_2O_5, 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.

3. Predicate Device Identification

Primary Predicate Device:

510(k) Number: K051705

Product Name: IPS E.MAX CAD

Submitter/Manufacturer: IVOCLAR VIVADENT, INC.

Reference Device:

510(k) Number: K222513

Product Name: Glass Ceramics

Submitter/Manufacturer: Yilink (Tianjin) Biotechnology Co., Ltd.

4. Substantially Equivalent Comparison

Table 1-

Parameters	New Device	Primary Predicate Device	Reference Device	Remark
510(k) Number	K230487	K051705	K222513	---
510(k) Owner	Fuzhou Rick Brown Biomaterials CO., LTD.	IVOCLAR VIVADENT, INC.	Yilink (Tianjin) Biotechnology Co., Ltd.	---
Device Name	Dental Lithium Disilicate Glass-Ceramic	IPS E.MAX CAD	Glass Ceramics	---
Product Code	EIH	EIH	EIH	Same
Regulation No.	21 CFR 872.6660	21 CFR 872.6660	21 CFR 872.6660	Same
Class	2	2	2	Same
Intended 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.	e IPS e.max CAD is a CAD/CAM machinable glass ceramic based on lithium disilicate for the preparation of full ceramic crowns, inlays, onlays, and full ceramic 3-unit anterior bridges.	Glass Ceramics are indicated for fabricating all-ceramic restorations such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.	Similar
Material	SiO_2, Li_2O, K_2O, Al_2O_3, P_2O_5, ZrO_2 and other oxides	SiO_2, Li_2O, K_2O, P_2O_5, ZrO_2 , ZnO and other oxides	SiO_2, Li_2O, K_2O, Al_2O_3 and other oxides	Similar
Environment of use	Prescription Use	Prescription Use	Prescription Use	Same
Design	Cuboid, Cylinder	Block	Block	Similar
Color	Translucency: High Translucency (HT)	Translucency: High Translucency (HT)	Various	Similar

	Medium translucency (MT) Low Translucency (LT) Medium Opacity (MO) High Opacity (HO) Shades: HT/MT/LT: 16 A-D and 4 Bleach MO: 5 MO 0 – MO 4 HO: 3 HO 0 – HO 2	Low Translucency (LT) Medium Opacity (MO) Shades: HT/LT: 16 A-D and 4 Bleach MO: 5 MO 0 – MO 4		
Crystallization State as Supplied	Cuboid: Partially crystallized, final crystallization done by dental laboratory Cylinder: Fully crystallized	Partially crystallized, final crystallization done by dental laboratory	Not publicly available	Similar
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Single Use	Yes	Yes	Yes	Same
Types, Class (ISO 6872:2015)	Type II, Class 3	Type II, Class 3	Type II, Class 2	Same
Freedom from Extraneous materials	Free from extraneous materials	Free from extraneous materials	Not Reported	Same
Flexural Strength	≥300MPa	≥300MPa	≥100MPa	Same
Linear thermal Expansion coefficient	(9.8±0.5) x 10^{-6}/K	(10.5±0.5) x 10^{-6}/K	(11±0.5) x 10^{-6}/K	Similar
Glass Transition Temperature	495±20℃	Not Reported	520±20℃	Similar
Chemical Solubility	< 100μg/cm^2	< 100μg/cm^2	Not Reported	Same
Shrinkage factor	Length: 1.0011 Width: 1.0018 Height: 1.0036	Not Reported	< 100μg/cm^2	Similar
Radioactivity	Meets ISO 6872 requirements ≤ 1.0 Bq/g of ^{238}U	Meets ISO 6872 requirements ≤ 1.0 Bq/g of ^{238}U	Meets ISO 6872 requirements ≤ 1.0 Bq/g of ^{238}U	Same
Biocompatibility	Conform to ISO 7405: 2018	Conform to ISO 10993-1	Conform to ISO 10993	Similar

The proposed device has the similar indication for use as the predicate devices as well as comparable technical and biocompatibility properties and characteristics, and the minor differences don't raise any additional questions for safety and effectiveness. Therefore, the proposed device is substantially equivalent to the predicate devices.

5. Non-clinical Testing Summary

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.

6. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission, the Dental Lithium Disilicate Glass-Ceramic, are as safe, as effective, and performs as well as the legally marketed predicate devices.