March 20, 2024

Prismatik Dentalcraft, Inc.
Su Hyun Park
Regulatory Affairs Manager
2144 Michelson Drive
Irvine, California 92612

Re: K240574
Trade/Device Name: BruxZir® Radiant
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: February 19, 2024
Received: March 1, 2024

Dear Su Hyun Park:

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 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240574

Device Name

BruxZir® Radiant

Indications for Use *(Describe)*

The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.

Contraindication: This device is contraindicated for dental restorations greater than 3-units in length.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PRISMATIK DENTALCRAFT, INC.

510(k) Summary

Date Prepared: February 29, 2024

CONTACT DETAILS (21 CFR 807.92(a)(1))

Applicant Name: Prismatik Dentalcraft, Inc.

Applicant Address: 2144 Michelson Drive, Irvine, CA 92612, USA

Applicant Contact Telephone: 949-863-5479

Applicant Contact: So Hyun Park, Regulatory Affairs Manager, MS

Applicant Contact Email: so.park@glidewelldental.com

DEVICE NAME (21 CFR 807.92(a)(2))

Device Trade Name: BruxZir® Radiant

Common Name: Zirconia milling block or dental CAD/CAM block

Classification Name: Porcelain powder for clinical use

Regulation Number: 872.6660

Regulatory Class: Class II

Product Code: EIH

LEGALLY MARKETED PREDICATE DEVICE (21 CFR 807.92(a)(3))

Predicate 510(k) #: K150872

Predicate Trade Name: BruxZir® Anterior

Product Code: EIH

DEVICE DESCRIPTION SUMMARY (21 CFR 807.92(a)(4))

BruxZir® Radiant are zirconia milling blanks used to produce highly esthetic zirconia dental restorations. The high esthetics and high strength of BruxZir® Radiant restorations make them viable for use in all regions of the mouth. The manufactured dental restorations are made utilizing a CAD/CAM system for design and manufacture. The designed and manufactured dental restorations are then sintered at a high temperature. BruxZir® Radiant Blanks are available in 6 shades, Brite, White, 100, 200, 300, 400, that can be easily adjusted to match the final shade.

INTENDED USE/INDICATIONS FOR USE (21 CFR 807.92(a)(5))

BruxZir® Radiant is intended to be used in fabrication of dental restorations for the purpose of restoring chewing function. The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior locations.

This device is contraindicated for dental restorations greater than 3-units in length.

INDICATIONS FOR USE COMPARISON (21 CFR 807.92(a)(5))

The subject device, BruxZir® Radiant, has the same indications for use as the predicate device, BruxZir® Anterior (K150872). Both devices are indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior locations. Both the subject device, BruxZir® Radiant, and predicate device, BruxZir® Anterior (K150872), are also contraindicated for dental restorations greater than 3-units in length.

TECHNOLOGICAL COMPARISON (21 CFR 807.92(a)(6))

The subject device, BruxZir® Radiant, is substantially equivalent in technical characteristics to the predicate device, BruxZir® Anterior (K150872) in terms of overall design principles, material, and performance.

The subject device, BruxZir® Radiant, is similar in terms of overall design to the predicate device, BruxZir® Anterior (K150872). The subject device, BruxZir® Radiant, is only offered in one style (Zeno) milling blank whereas the predicate device, BruxZir® Anterior (K150872), is offered in various designs. There is no change in packaging for a milling blank. The fundamental principle of operation of the subject device, BruxZir® Radiant, and the predicate device, BruxZir® Anterior (K150872), is the same. The manufactured dental restorations are made utilizing a CAD/CAM system for design and manufacture. The designed and manufactured dental restorations are then sintered at a high temperature. Although no color needs to be added additionally, pre-coloring before sintering and/or basic staining and glazing techniques may be used after sintering to achieve the desired shade. Also, the change in the manufacturing process from the press process to the colloidal process does not affect the mechanical properties of the final finished device.

The subject device, BruxZir® Radiant, is similar in terms of material composition to the predicate device, BruxZir® Anterior (K150872). The main ceramic component is composed of yttria-stabilized zirconia with varying trace amount of colorants. As the generic type of material has not changed, it does not alter the performance specifications of the subject device. The slight differences in overall chemical composition do not affect the biocompatibility and performance characteristics.

The technological comparison table below outlines and provides the similarities between the subject device, BruxZir® Radiant, and the predicate device, BruxZir® Anterior (K150872). Both the subject device and the predicate device have similar physical/mechanical and biocompatibility properties that met the requirements of ISO 6872:2015/Amd 1:2018 (Type

II, Class 4) and ISO 10993. Any differences between the subject device and the predicate device do not raise any new concerns of safety and effectiveness.

Attributes		Subject Device (TBD)	Predicate Device (K150872)	Comparison
Device Name		BruxZir® Radiant	BruxZir® Anterior	N/A
Manufacturer		Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Product Code		EIH	EIH	Same
Prescription Device		Yes	Yes	Same
Indications for Use		The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.	The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.	Same
Contraindications		This device is contraindicated for dental restorations greater than 3-units in length.	This device is contraindicated for dental restorations greater than 3-units in length.	Same
Design Characteristic	Chemical Composition	The main ceramic component is composed of yttria-stabilized zirconia. The different shades have varying trace colorants as required to match the desired shades.	The main ceramic component is composed of yttria-stabilized zirconia. The different shades have varying trace colorants as required to match the desired shades.	Similar; Different yttria proportion of the main ceramic components and different oxide colorants for the subject device.
	Design	Various sizes and thicknesses	Various sizes and thicknesses	Similar; Different sizes and thicknesses are offered for the subject device.
	Principle of Operation	The manufactured dental restorations are made utilizing a CAD/CAM system for design and manufacture. The designed and manufactured dental restorations are then	The manufactured dental restorations are made utilizing a CAD/CAM system for design and manufacture. The designed and manufactured dental restorations are then	Same

Attributes		Subject Device (TBD)	Predicate Device (K150872)	Comparison
		sintered at a high temperature. The final target shades can be easily adjusted to match the final shade.	sintered at a high temperature. The final target shades can be easily adjusted to match the final shade.	
	Shades	Brite, White, 100, 200, 300, 400	White, 150, 250, 350, 450, 550	Different; different shades are offered for the subject device.
	Final Vita Shades	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4	Same
	Flexural Strength	>500 MPa	>500 MPa	Same
	Coefficient of Thermal Expansion (CTE/25-500°C)	10-11x10^{-6}/°C	10-11x10^{-6}/°C	Same
	Chemical Solubility	<100 µg/cm²	<100 µg/cm²	Same
	Radioactivity	The activity concentration of Uranium-238 is no more than 1.0 Bq/g.	The activity concentration of Uranium-238 is no more than 1.0 Bq/g.	Same
	Biocompatibility	Biocompatible and non-toxic	Biocompatible and non-toxic	Same
	Sterility	Non-sterile	Non-sterile	Same
	Manufacturing Process	Colloidal Process	Biaxial Pressing Process	Different manufacturing process

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS 21 CFR 807.92(b))

Design verification according to BruxZir® Radiant Design Verification Protocol was conducted by Prismatik Dentalcraft, Inc. The tests conducted are listed below:

- Flexural Strength according to ISO 6872:2015/Amd 1:2018
- Translucency
- Visual Shade Evaluation
- Color Consistency
- Coefficient of Thermal Expansion according to ISO 6872:2015/Amd 1:2018
- Chemical Solubility according to ISO 6872:2015/Amd 1:2018
- Radioactivity according to ISO 6872:2015/Amd 1:2018
- Biocompatibility according to ISO 10993-1:2018 and ISO 10993-5:2009

No clinical data is included in this submission.

The test samples were made using the standard manufacturing process and QC process for BruxZir® Radiant to ensure that the test samples meet the following criteria for the finished device:

- Flexural Strength must be greater than 500 MPa after sintering, as measured per ISO 6872:2015/Amd 1:2018, Type II Class 4.
- Translucency of each formulation must be higher than the values shown in the table below at 700nm.

Shade	BruxZir® Radiant % Translucency at 700nm
White	>59
Brite	>65
100	>57
200	>57
300	>57
400	>57

- Grade of "Pass" for Visual Shade Match for all shades.
- Color consistency ΔE calculation needs to be less than 2.00 between samples measured.
- The Coefficient of Thermal Expansion must be between 10-11 x 10^{-6}/°C and the standard deviation of CTE must be no greater than 0.5 x 10^{-6}/°C per ISO 6872:2015/Amd 1:2018.
- The solubility must be lower than 100 µg/cm^2 per ISO 6872:2015/Amd 1:2018.
- The activity concentration of Uranium-238 must not exceed 1.0 Bq·g^{-1} per ISO 6872:2015/Amd 1:2018.
- BruxZir® Radiant must be biocompatible, safe, and non-toxic.

The results of the verification activities confirmed that the design of the subject device met all the predetermined criteria according to the design specifications. The results of the testing were used to address questions related to substantial equivalence based on differences in technological features between the subject device, BruxZir® Radiant, and the predicate device, BruxZir® Anterior (K150872), by verifying that the modified device met all the design specification requirements, and the design changes were implemented successfully without causing any unexpected issues.