May 1, 2024

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

Re: K240882
Trade/Device Name: BruxZir® Esthetic
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: March 29, 2024
Received: April 1, 2024

Dear So 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 (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.

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,

FDA Bobak Shirmohammadi -S

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

K240882

Device Name

BruxZir® Esthetic

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.

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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PRISMATIK DENTALCRAFT, INC.

K240882 - 510(k) Summary

Date Prepared: March 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® Esthetic

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) #: K231425

Predicate Trade Name: BruxZir® Esthetic

Product Code: EIH

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

BruxZir® Esthetic blanks are zirconia milling blanks used for the production of highly esthetic zirconia dental restorations. The high esthetics and high strength of BruxZir® Esthetic 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® Esthetic blanks are available in white, bleach, and pre-shaded varieties that can be easily adjusted to match the final shade.

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

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

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

The subject device, BruxZir® Esthetic, has the same indications for use as the predicate device, BruxZir® Esthetic (K213425). Both devices are indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.

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

The subject device, BruxZir® Esthetic, is substantially equivalent in technical characteristics to the predicate device, BruxZir® Esthetic (K213425) in terms of overall design principles, material, and performance.

The subject device, BruxZir® Esthetic, is similar in terms of overall design to the predicate device, BruxZir® Esthetic (K213425). The subject device, BruxZir® Esthetic, is offered in a milling blank and GL Single Unit design to be used for milling single-unit restorations. The predicate device, BruxZir® Esthetic (K213425), is offered in the same designs with the addition of the GL Bridge Block, which is designed to be used for milling bridges (restorations of three or more units). The fundamental principle of operation of the subject device, BruxZir® Esthetic, and the predicate device, BruxZir® Esthetic (K213425), 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 (slip casting) does not affect the mechanical properties of the final finished device.

The subject device, BruxZir® Esthetic, is similar in terms of material composition to the predicate device, BruxZir® Esthetic (K213425). 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® Esthetic, and the predicate device, BruxZir® Esthetic (K213425). Both the subject device and the predicate device have similar physical/mechanical and biocompatibility properties that met the requirements of ISO 6875:2015/Amd 1:2018 (Type II, Class 5) 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 (K240882)	Predicate Device (K213425)	Comparison
Device Name		BruxZir® Esthetic	BruxZir® Esthetic	Same
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
Design Characteristics	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 size and thicknesses	Various size and thicknesses	Similar; Different sizes and thicknesses 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 sintered at a high temperature. No color needs to be added before sintering. The final target shades are achievable without additional coloring steps.	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. No color needs to be added before sintering. The final target shades are achievable without additional coloring steps.	Same

Attributes		Subject Device (K240882)	Predicate Device (K213425)	Comparison
	Shade	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, White, Bleach	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, White, BL1, BL3	Similar; Fewer bleach 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, White, Bleach	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, White, BL1, BL3	Similar; Fewer final target shades are offered for the subject device.
	Flexural Strength	>800 MPa	>800 MPa	Same
	Coefficient of Thermal Expansion (CTE/25-500°C)	10-11 x 10^{-6} /°C	10-11 x 10^{-6} /°C	Same
	Chemical Solubility	<100 µg/cm^2	<100 µg/cm^2	Same
	Radioactivity	The activity concentration of Uranium-238 is no more than 1.0 Bq/g^{-1}.	The activity concentration of Uranium-238 is no more than 1.0 Bq/g^{-1}.	Same
	Biocompatibility	Biocompatible and non-toxic	Biocompatible and non-toxic	Same
	Sterility	Non-sterile	Non-sterile	Same
	Manufacturing Process	Colloidal process	Bi-axial pressing process	Different manufacturing process

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

Design verification according to BruxZir® Esthetic 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
- Visual Shade Evaluation
- Color Consistency
- Translucency
- 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

No clinical data is included in this submission.

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

- Flexural Strength must be greater than 800 MPa after sintering, as measured per ISO 6872:2015/Amd 1:2018, Type II Class 5.
- Grade of "Pass" for Visual Shade Match for all shades.
- Color consistency ΔE calculation needs to be less than 2.00 between samples measured.
- Translucency of each formulation must be within 1 % of the equivalent BruxZir Anterior-16 shade at 700nm.
- 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® Esthetic 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® Esthetic, and the predicate device, BruxZir® Esthetic (K213425), by verifying that the modified device met all the design specification requirements, and the design changes were implemented successfully without causing any unexpected issues.