



January 30, 2026

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

Re: K254283
Trade/Device Name: BruxZir® Shaded 16 PLUS
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: December 30, 2025
Received: December 31, 2025

Dear Park So Hyun:

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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K254283

?

Please provide the device trade name(s).

?

BruxZir® Shaded 16 PLUS

Please provide your Indications for Use below.

?

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

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary - K254283

Date Prepared: December 30, 2025

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: 949-535-3038

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

Applicant Contact Email: so.park@glidewelldental.com

Secondary Contact: Shelly Gallup, Sr. VP – RA/QA

Secondary Contact Email: shelly.gallup@glidewelldental.com

Secondary Contact Telephone: 949-533-9412

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

Device Trade Name: BruxZir® Shaded 16 PLUS

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) #: K130924

Predicate Device Trade Name: BruxZir® Shaded

Product Code: EIH

Reference 510(k) #: K220816

Reference Device Trade Name: BruxZir® NOW

Product Code: EIH

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

BruxZir Shaded 16 PLUS blanks are used for the production of full-contour zirconia and zirconia-based substructures for crowns and bridges (restorations). Multiple thicknesses and shades (A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL3, and White) are

available for milling into BruxZir restorations. The manufactured restorations are made utilizing the CAD/CAM system for design and manufacturing. The designed and manufactured restorations are then sintered and glazed. BruxZir Shaded 16 PLUS restorations are designed to match the body shade in the glazed state; however, precolor and stain should be applied if polychromatic (gingival to incisal) blending or other esthetic effects are desired. The sintered material exhibits maximum strength, color, and translucency similar to natural dentition.

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[®] Shaded 16 PLUS, has the same indications for use as the predicate device, BruxZir[®] Shaded (K130924). 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[®] Shaded 16 PLUS, is substantially equivalent in technical characteristics to the predicate device, BruxZir[®] Shaded (K130924) in terms of overall design principles, material, and performance.

The subject device, BruxZir[®] Shaded 16 PLUS, is similar in terms of overall design to the predicate device, BruxZir[®] Shaded (K130924). The predicate device, BruxZir[®] Shaded (K130924), is only offered in a milling blank whereas the subject device, BruxZir[®] Shaded 16 PLUS, is offered in different designs other than a milling blank such as GL Single Unit and GL Bridge Block, which are designed to be used for milling single-unit restorations and bridges (restorations of three or more units), respectively. The fundamental principle of operation of the subject device, BruxZir[®] Shaded 16 PLUS, and the predicate device, BruxZir[®] Shaded (K130924), 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 to either device before sintering, basic staining and glazing techniques need to be used after sintering to achieve the desired shade for the predicate device, BruxZir[®] Shaded (K130924). On the other hand, the final shades are achievable without additional coloring steps for the subject device, BruxZir[®] Shaded 16 PLUS.

The subject device, BruxZir[®] Shaded 16 PLUS, is similar in terms of material composition to the predicate device, BruxZir[®] Shaded (K130924). The main ceramic component is composed of yttria-stabilized zirconia with varying trace components 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. Also, the change in the manufacturing process from colloidal process (slip casting) to press process does not affect the mechanical properties of the final finished device.

The technological comparison table below outlines and provides the similarities between the subject device, BruxZir[®] Shaded 16 PLUS, and the predicate device, BruxZir[®] Shaded (K130924).

Both the subject device and the predicate device have similar physical/mechanical and biocompatibility properties that met the requirements of ISO 6875:2024 (Type II, Class 5) and ISO 10993-1:2025 and ISO 10993-5:2009. 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 (K130924)	Comparison
Device Name		BruxZir® Shaded 16 PLUS	BruxZir® Shaded	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
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; Similar yttria proportion of the main ceramic components (~3Y) and different 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 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. Basic staining and glazing techniques need to be used after sintering to achieve the desired final target shades.	Similar; The target shades are achievable without additional coloring steps for the subject device.

Attributes		Subject Device (TBD)	Predicate Device (K130924)	Comparison
	Shades	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, BL1, BL3, White	100, 200, 300, 400	Different; Final VITA shades are achievable without additional coloring steps for the subject device. More 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, BL1, BL3, White	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4	Similar; More 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	Press process	Colloidal process	Different manufacturing process

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

Design verification and validation were conducted by Prismatic Dentalcraft, Inc. The tests conducted are listed below.

- Flexural Strength according to ISO 6872:2024
- Visual Shade Match
- Color Consistency
- Coefficient of Thermal Expansion according to ISO 6872:2024
- Chemical Solubility according to ISO 6872:2024
- Radioactivity according to ISO 6872:2024

- Packaging Validation according to ASTM D4169-23e1
- Biocompatibility according to ISO 10993-1:2025 and ISO 10993-5:2009

No clinical data is included in this submission.

The test samples were manufactured using the standard, validated manufacturing and quality control processes for BruxZir® Shaded 16 PLUS to ensure that the final finished devices met the following specified acceptance criteria.

- Flexural Strength must be greater than 800 MPa after sintering, as measured per ISO 6872:2024, Type II Class 5.
- Grade of “Pass” for Visual Shade Match for all shades.
- Color consistency within a block, between blocks of the same batch and between batches – ΔE calculation needs to be less than 2.00 between samples measured.
- The Coefficient of Thermal Expansion must be between $10-11 \times 10^{-6}/^{\circ}\text{C}$ and the standard deviation of CTE must be no greater than $0.5 \times 10^{-6}/^{\circ}\text{C}$ per ISO 6872:2024.
- The solubility must be lower than $100 \mu\text{g}/\text{cm}^2$ per ISO 6872:2024.
- The activity concentration of Uranium-238 must not exceed $1.0 \text{ Bq}\cdot\text{g}^{-1}$ per ISO 6872:2024.
- Must be biocompatible, safe, and non-toxic.

The results of the verification and validation activities confirmed that the design of the subject device met all the predetermined criteria according to the design specifications. The testing results were used to support substantial equivalence by addressing differences in technological characteristics between the subject device, BruxZir® Shaded 16 PLUS, and the predicate device, BruxZir® Shaded (K130924). Testing confirmed that the modified device met all the design specifications and that the design changes were implemented successfully without introducing any unexpected issues.

The subject device, BruxZir® Shaded 16 PLUS, is substantially equivalent to the predicate device, BruxZir® Shaded (K130924), with respect to intended use, indications for use, fundamental technological characteristics, including design, materials and principles of operation. Based on this information, these modifications do not raise any new questions of safety and effectiveness when compared to the predicate device.