September 3, 2025

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

Re: K252446
Trade/Device Name: BruxZir® NOW
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: August 1, 2025
Received: August 4, 2025

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.

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
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Respiratory, ENT, and Dental Devices
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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.

510(k) Number *(if known)*
K252446

Device Name
BruxZir® NOW

Indications for Use *(Describe)*
The device is used for dental restorations using different CAD/CAM or manual milling machines. All blocks are processed through dental laboratories or by dental professionals.

Contraindication: BruxZir® NOW Bridge Block design is limited to a maximum of four units with a maximum of two pontics between pillars.

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.

K252446

510(k) Summary

Date Prepared: August 1, 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: 949-863-5479

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

Applicant Contact Email: so.park@glidewelldental.com

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

Secondary Contact Email: shelly.gallup@glidewelldental.com

Secondary Contact Phone: 949-222-3590

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

Device Trade Name: BruxZir® NOW

Common Name: Zirconia Milling Block or Dental CAD/CAM Block

Classification Name: Porcelain powder for clinical use

Regulation Number: 872.6660

Product Code: EIH

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

Predicate 510(k) #: K220816

Predicate Trade Name: BruxZir® NOW

Product Code: EIH

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

BruxZir® NOW is a pre-shaded, fully sintered zirconia CAD/CAM block used for fabricating single-unit or multiple-unit dental restorations. BruxZir® NOW is used for fabricating single-unit dental restorations, while BruxZir® NOW Bridge Block is used for fabricating multiple-unit dental restorations. BruxZir® NOW is available in the following shades: Bleach White, Bleach 1, Bleach 3, and 16 VITA Classical shades (A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4). BruxZir® NOW Bridge Block is available in the following 6 VITA Classical shades: A1, A2, A3, B1, C2, D2. The method of fabricating the restoration is with CAD/CAM milling systems.

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

The device is used for dental restorations using different CAD/CAM or manual milling machines. All blocks are processed through dental laboratories or by dental professionals.

Contraindication: BruxZir® NOW Bridge Block design is limited to a maximum of four units with a maximum of two pontics between pillars.

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

The subject device, BruxZir® NOW, has the same indications for use as the predicate device, BruxZir® NOW (K220816). Both devices are indicated for use for dental restorations using different CAD/CAM or manual milling machines. All blocks are processed through dental laboratories or by dental professionals. The subject device, BruxZir® NOW, also has the addition of a contraindication for use. BruxZir® NOW Bridge Block design is limited to a maximum of four units with a maximum of two pontics between pillars.

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

The subject device, BruxZir® NOW, is substantially equivalent in technical characteristics to the predicate device, BruxZir® NOW (K220816), in terms of overall design principles and performance.

The subject device, BruxZir® NOW, is unchanged in terms of overall design to the predicate device, BruxZir® NOW (K220816). Both devices are offered in a fully sintered block form in two sizes for single and multiple-unit restorations based on the anatomical rendering of the patient's teeth using CAD/CAM equipment.

The subject device, BruxZir® NOW, is unchanged in terms of material composition to the predicate device, BruxZir® NOW (K220816). The main ceramic component is composed of yttria-stabilized zirconia with varying trace amounts of colorants. There is no difference in overall chemical composition and therefore, does not affect the biocompatibility and performance characteristics.

The performance specifications, fundamental scientific technology, and intended use of the subject device, BruxZir® NOW, are unchanged from the predicate device, BruxZir® NOW (K220816).

The technological comparison table below outlines and provides the similarities between the subject device, BruxZir® NOW, and the predicate device, BruxZir® NOW (K220816). Both the subject device and the predicate device have the same physical/mechanical and biocompatibility properties that met the requirements of ISO 6872:2024 (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.

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

Technological Characteristics		Subject Device (TBD)	Predicate Device (K220816)	Comparison
Device Name		BruxZir® NOW	BruxZir® NOW	N/A
Manufacturer		Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Product Code		EIH	EIH	Same
Prescription Device		Yes	Yes	Same
Indications for Use		BruxZir® NOW is used for dental restorations using different CAD/CAM or manual milling machines. All blocks are processed through dental laboratories or by dental professionals.	BruxZir® NOW is used for dental restorations using different CAD/CAM or manual milling machines. All blocks are processed through dental laboratories or by dental professionals.	Same
Contraindication		BruxZir® NOW Bridge Block design is limited to a maximum of four units with a maximum of two pontics between pillars.	None.	Different; the subject device includes the addition of a contraindication for use of the bridge block design.
Design Characteristics	Chemical Composition	The device is composed of Yttria-stabilized zirconia (YSZ) and pigments to achieve the desired shades.	The device is composed of Yttria-stabilized zirconia (YSZ) and pigments to achieve the desired shades.	Same
	Design	Fully sintered zirconia block available in block form in 2 sizes for single and multiple-unit restorations	Fully sintered zirconia block available in block form in 2 sizes for single and multiple-unit restorations	Same
	Shades	BruxZir® NOW is available in the following shades: Bleach White, Bleach 1, Bleach 3, and 16 VITA Classical shades (A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4). BruxZir® NOW Bridge Block is available in the following 6 VITA Classical shades: A1, A2, A3, B1, C2, D2.	BruxZir® NOW is available in the following shades: Bleach White, Bleach 1, Bleach 3, and 16 VITA Classical shades (A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4). BruxZir® NOW Bridge Block is available in the following 6 VITA Classical shades: A1, A2, A3, B1, C2, D2.	Same

Technological Characteristics		Subject Device (TBD)	Predicate Device (K220816)	Comparison
	Flexural Strength	>800 MPa Type II Class 5 per ISO 6872:2024	>800 MPa Type II Class 5 per ISO 6872:2024	Same
	Biocompatibility	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1	Same
	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.	The activity concentration of Uranium-238 is no more than 1.0 Bq/g.	Same

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

No changes were made to any physical component of BruxZir® NOW. The performance specifications, fundamental scientific technology, and intended use of the subject device, BruxZir® NOW, are unchanged from the predicate device, BruxZir® NOW (K220816).

The proposed device is BruxZir® NOW with a labeling modification. Specifically, the modification involves the addition of a contraindication pertaining to the use of the device in the BruxZir® NOW Bridge Block design, which led to a Change Being Effected (CBE) 510(k). A risk-based assessment was conducted and identified a specific use of BruxZir® NOW Bridge Blocks to a maximum of four units with a maximum of two pontics between pillars. The labeling change was added to help remind the practitioner of the limitation in bridge design imposed by the size of the block, rather than to address any substantial safety risks of the device that restrict its use. It is not associated with any new safety concerns or risk mitigation strategies, nor does it impact the previously cleared indications for use under the existing 510(k) for BruxZir® NOW (K220816).

Following the FDA Guidance, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, a Change Being Effected (CBE) 510(k) is appropriate when the change is only the addition of a contraindication. Per the FDA Guidance, the Special 510(k) Program, a Special 510(k) is appropriate when it is a design or labeling change to the manufacturer's own device and performance data are not needed to evaluate the change.

Design verification for BruxZir® NOW (K220816) was previously conducted by Prismatik Dentalcraft, Inc. and is not required for this submission. The following non-clinical data has already been submitted under BruxZir® NOW (K220816) to demonstrate substantial equivalence:

- Flexural Strength according to ISO 6872:2024
- Solubility according to ISO 6872:2024
- Shade evaluation
- Biocompatibility according to ISO 10993-1:2018
- Radioactivity according to ISO 6872:2024

- Packaging Validation according to ASTM D4169-16

No additional verification or validation is necessary to evaluate this change. No clinical data is included in this submission.

The subject device, BruxZir® NOW, is substantially equivalent to the predicate device, BruxZir® NOW (K220816), in regard to intended use, indications for use, fundamental technology including design, materials, manufacturing methods and operational principles. Based on this information, the modification does not raise any new issues regarding the safety and effectiveness of the device when compared to its predicate.