February 25, 2025

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

Re: K250223
Trade/Device Name: BruxZir® Esthetic NOW
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: January 24, 2025
Received: January 27, 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,

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)*

K250223

Device Name

BruxZir® Esthetic NOW

Indications for Use *(Describe)*

BruxZir® Esthetic 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.

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.

PRISMATIK DENTALCRAFT, INC.

K250223

510(k) Summary

I. SUBMITTER

Prismatik Dentalcraft, Inc.
2144 Michelson Drive,
Irvine, CA 92612, USA

Primary Contact Person: So Hyun Park, Regulatory Affairs Manager
Email: so.park@glidewelldental.com
Phone: (949) 863-5479

Secondary Contact Person: Maria Wagner, Sr, Regulatory Affairs Manager
Email: maria.wagner@glidewelldental.com
Phone: (949) 838-1321

Date Prepared: January 24, 2025

II. DEVICE

Name of Device:	BruxZir® Esthetic NOW
Common Name or Usual Name:	Zirconia Milling Block or Dental CAD/CAM Block
Classification Name:	Porcelain powder for clinical use (21 CFR 872.6660)
Regulatory Class:	Class II
Product Code:	EIH

III. PREDICATE DEVICE

BruxZir® NOW (K220816)

IV. DEVICE DESCRIPTION

BruxZir® Esthetic NOW is a chairside zirconia material offering enhanced esthetic performance. These pre-shaded, fully sintered zirconia CAD/CAM blocks are used by dentists in the construction of custom-made dental restorations that require no sintering, staining, glazing or polishing.

V. INDICATIONS FOR USE

BruxZir® Esthetic 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological Characteristics		Subject Device (K250223)	Predicate Device (K220816)	Comparison
Device Name		BruxZir® Esthetic NOW	BruxZir® NOW	N/A
Manufacturer		Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Product Code		EIH	EIH	Same
Prescription Device		Yes	Yes	Same
Intended Use		BruxZir® Esthetic NOW is intended to be used in fabrication of dental restorations such as crowns for the purpose of restoring chewing function.	BruxZir® NOW is intended to be used in fabrication of dental restorations such as crowns and bridges for the purpose of restoring chewing function.	Similar; Due to the device design, the subject device can only be fabricated into a single-unit restoration.
Indications for Use		BruxZir® Esthetic 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 except for the device trade name
Design Characteristics	Material 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.	Similar; Both the subject device and the predicate device are composed of Yttria-stabilized zirconia as the primary component and the desired shades are achieved by using different pigments.
	Design	Fully sintered zirconia block available in block form in 2 sizes for single-unit restoration (anterior and posterior geometries)	Fully sintered zirconia block available in block form in 2 sizes for single and multiple-unit restorations	Similar; Due to the device design, the subject device can only be fabricated into a single-unit restoration.
	Shades	BruxZir® Esthetic NOW is available in the following shades: Bleach White, Bleach 1 and 16	BruxZir® NOW is available in the following shades: Bleach White, Bleach 1,	Similar; The subject device and the predicate device are offered in Bleach

Technological Characteristics		Subject Device (TBD)	Predicate Device (K220816)	Comparison
		VITA Classical Shades (A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4)	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.	shades and 16 VITA Classical shades. The subject device is not offered in Bleach 3 shade.
	Flexural Strength	>800 MPa Type II Class 5 per ISO 6872:2024	>800 MPa Type II Class 5 per ISO 6872:2015/Amd 1:2018	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

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device, BruxZir® Esthetic NOW, is substantially equivalent to the predicate device, BruxZir® NOW (K220816), in intended use, indications for use, material, design principles and technological characteristics.

The subject device, BruxZir® Esthetic NOW, has similar intended use as the predicate device, BruxZir® NOW (K220816), as the device is used in fabrication of dental restorations such as crowns for the purpose of restoring chewing function. Due to the device design, the subject device, BruxZir® Esthetic NOW, can only be fabricated into a single-unit restoration. The subject device, BruxZir® Esthetic NOW, has the same indications for use statement (IFUS) as the predicate device, BruxZir® NOW (K220816), except for the device trade name. Both the subject device and the predicate device are dental restorative materials indicated for fabrication of dental restorations using CAD/CAM or manual milling machines. All blocks are processed through dental laboratories or by dental professionals.

The subject device, BruxZir® Esthetic NOW, is substantially equivalent to the predicate device, BruxZir® NOW (K220816), in technological characteristics. The same mechanical property testing in terms of flexural strength that was conducted on the predicate device, BruxZir® NOW (K220816), was also conducted on the subject device, BruxZir® Esthetic NOW, according to ISO 6872:2024. The flexural strength of the subject device, BruxZir®

Esthetic NOW, passed the threshold of performance criteria in ISO 6872 for Type II Class 5.

The subject device, BruxZir® Esthetic NOW, and the predicate device, BruxZir® NOW (K220816), are similar in material composition. Both devices utilize Yttria-stabilized zirconia as the base material and pigments. Despite the differences in the pigments used to achieve the desired shades, the slight differences in chemical formulation do not affect the safety and effectiveness of the device as verified and validated by the biocompatibility and performance testing.

The subject device, BruxZir® Esthetic NOW, and the predicate device, BruxZir® NOW (K220816), are substantially equivalent in terms of design. Both are offered in a fully sintered block form in different shapes and shades and are used to make final dental restorations based on the anatomical rendering of the patient's teeth using CAD/CAM equipment.

VII. PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence include:

- Flexural Strength according to ISO 6872:2024
- Chemical Solubility according to ISO 6872:2024
- Coefficient of Thermal Expansion (CTE) 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 D4169-22

No clinical data is included in this submission.

Flexural Strength

Flexural strength was tested on the worst-case shades and additional shade for BruxZir® Esthetic NOW. The average flexural strength of each worst-case yielded the results above the minimum threshold of 800 MPa, which is the value to be achieved for Type II Class 5 ceramic product according to ISO 6872:2024. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, BruxZir® Esthetic NOW, and predicate device, BruxZir® NOW (K220816).

Chemical Solubility

The worst cases of BruxZir® Esthetic NOW were tested for solubility and the measured values were <100 $\mu g/cm^2$ meeting the ISO 6872:2024 requirement. The result of the testing was used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, BruxZir® Esthetic NOW, and predicate device, BruxZir® NOW (K220816).

Coefficient of Thermal Expansion (CTE)

The worst cases of BruxZir® Esthetic NOW were tested for Coefficient of Thermal Expansion and the measured values were between 10-11 x 10^{-6}/°C and a standard deviation of CTE no greater than 0.5 x 10^{-6}/°C meeting the ISO 6872:2024 requirement. The result of the testing was used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, BruxZir® Esthetic NOW, and predicate device, BruxZir® NOW (K220816).

Shade Evaluation

All shades offered for BruxZir® Esthetic NOW were evaluated by the qualified evaluators using the sample dental restorations milled from the final sintered products against the corresponding VITA Classical shade guide and reference Bleach shade guide. Evaluations concluded that BruxZir® Esthetic NOW meets shade match requirements and works as intended. The results of the testing were used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, BruxZir® Esthetic NOW, and predicate device, BruxZir® NOW (K220816).

Biocompatibility

Biological evaluation within a risk management process was performed in accordance with ISO 10993-1:2018 and ISO 14971:2019. Based on the cytotoxicity testing results from the subject device, BruxZir® Esthetic NOW, it was determined that there is no biocompatibility concern regarding yttria concentration, colorants, or other elements. The results of the testing were used to address questions related to substantial equivalence based on differences in chemical composition between the subject device, BruxZir® Esthetic NOW, and the predicate device, BruxZir® NOW (K220816).

Radioactivity

The worst cases of BruxZir® Esthetic NOW were tested for radioactivity and the measured values were below the Uranium-238 activity threshold of 1.0 $Bq \cdot g^{-1}$ set by the ISO 6872:2024 requirement. The result of the testing was used to address questions related to substantial equivalence based on differences in technical specifications between the subject device, BruxZir® Esthetic NOW, and predicate device, BruxZir® NOW (K220816).

Packaging Validation

The packaging validation was conducted to ensure that the packaging configurations for BruxZir® Esthetic NOW are suitable to withstand the distribution environment. Per ASTM D4169-22, BruxZir® Esthetic NOW was tested to check resistance against manual handling, vehicle stacking, loose load vibration, low pressure (high altitude) hazard, vehicle vibration, and concentrated impact. After the test, the shipping containers were visually inspected for any damage. It was determined that the respective packaging for BruxZir® Esthetic NOW blocks is suitable for use. The results of the testing were used to address questions related to substantial equivalence based on differences in product packaging

between the subject device, BruxZir® Esthetic NOW, and predicate device, BruxZir® NOW (K220816).

VIII. CONCLUSION

Based on the technological characteristics and non-clinical test data included in this submission, the subject device, BruxZir® Esthetic NOW, has been shown to be substantially equivalent to the predicate device, BruxZir® NOW (K220816).