August 2, 2022

Prismatik Dentalcraft, Inc.
So Hyun Park
Regulatory Affairs Manager
2144 Michelson Drive
Irvine, California 96212

Re: K220816
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: June 2, 2022
Received: June 3, 2022

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 (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,

For Michael E. Adjodha, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220816

Device Name
BruxZir® NOW

Indications for Use *(Describe)*
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.

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

I. SUMBITTER

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

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

Secondary Contact Person: Herbert Crane, VP RA/QA
Email: Herbert.crane@glidewelldental.com
Phone: (949) 222-3531

Date Prepared: July 19, 2022

II. DEVICE

Name of Device: BruxZir® 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

Primary Predicate Device: Perfit FS Dental Zirconia Fully Sintered Block (K203590)
Reference Device: BruxZir® Shaded (K130924)

IV. DEVICE DESCRIPTION

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.

V. 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological Characteristics		Subject Device (K220816)	Predicate Device (K203590)	Comparison
Device Name		BruxZir® NOW	Perfit FS Dental Zirconia Fully Sintered Block	N/A
Manufacturer		Prismatik Dentalcraft, Inc.	Vatech Acucera, Inc.	N/A
Product Code		EIH	EIH	Same
Prescription Device		Yes	Yes	Same
Intended Use		BruxZir® NOW is intended to be used in fabrication of dental restorations such as crowns and bridges for the purpose of restoring chewing function.	Perfit FS Dental Zirconia Fully Sintered Block is intended to be used in fabrication of dental restorations such as crowns and bridges for the purpose of restoring chewing function.	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.	Perfit FS Dental Zirconia Fully Sintered Block 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

Technological Characteristics		Subject Device (K220816)	Predicate Device (K203590)	Comparison
				desired shades are achieved by using different pigments.
	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 various sizes	Different; The subject device and the predicate device are offered in different shapes and sizes.
	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.	There are white zirconia products (White) and colored zirconia products, and colored zirconia is also divided into Monolayer (A1, A2, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4) color products, Shade multi-layer (ML A1/A2/A3, A1M, A2M, A3M, A3.5M, A4M) color products.	Different; The subject device and the predicate device are provided in different shades.
	Flexural Strength	>800 MPa Type II Class 5 per ISO 6872:2015/Amd 1:2018	≥ 500 MPa Type II Class 4 per ISO 6872:2015/Amd 1:2018	Different; The flexural strength of the subject device is >800 MPa, which is higher than the flexural strength of the predicate device. ISO classification is also different due to the difference in flexural strength.
	Biocompatibility	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1	Same
	Solubility	<100 µg/cm^2	<2000 µg/cm^2	Different; The subject device meets the ISO solubility requirement for Class 5.
	Radioactivity	The activity concentration of	The activity concentration of	Same

Technological Characteristics		Subject Device (K220816)	Predicate Device (K203590)	Comparison
		Uranium-238 is no more than 1.0 Bq/g.	Uranium-238 is no more than 1.0 Bq/g.	

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device, BruxZir® NOW, is substantially equivalent to the predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590) in intended use, indications for use, material, design principles and technological characteristics.

The subject device, BruxZir® NOW, has the same intended use as the predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590), as the material used in fabrication of dental restorations such as crowns and bridges for the purpose of restoring chewing function. The subject device, BruxZir® NOW, has the same indications for use statement (IFUS) as the predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590), 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® NOW, is substantially equivalent to the predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590), in technological characteristics. The same mechanical property testing in terms of flexural strength that was conducted on the predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590), was also conducted on the subject device, BruxZir® NOW, according to ISO 6872:2015/Amd 1:2018. The flexural strength of the subject device, BruxZir® NOW, passed the threshold of performance criteria in ISO 6872 for Type II Class 5. The flexural strength of the subject device, BruxZir® NOW, is higher than that of the predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590), which passed the threshold of performance criteria in ISO 6872 for Type II, Class 4.

The subject device, BruxZir® NOW, and the predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590), 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 by the biocompatibility and performance testing.

The subject device, BruxZir® NOW, and the predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590), 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 6872:2015/Amd 1:2018
- Solubility according to ISO 6872:2015/Amd 1:2018
- Shade evaluation
- Biocompatibility according to ISO 10993-1:2018
- Radioactivity according to ISO 6872:2015/Amd 1:2018
- Packaging Validation according to ASTM D4169-16

No clinical data is included in this submission.

Flexural Strength

Flexural strength was tested on the worst-case groups for two types of BruxZir® NOW and BruxZir® NOW Bridge Block. 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 6872:2015/Amd 1:2018. 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® NOW, and predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590).

Solubility

The worst case was tested for solubility and the measured value was <100 $\mu g/cm^2$ meeting the ISO 6872:2015/Amd 1:2018 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® NOW, and predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590).

Shade Evaluation

All shades offered for BruxZir® 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® 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® NOW, and predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590).

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® 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® NOW, and the predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590).

Radioactivity

BruxZir® NOW was tested to meet the radioactivity requirement of ISO 6872:2015/Amd 1:2018. BruxZir® NOW meets the radioactivity requirement since the sample measured below the Uranium-238 activity threshold of 1.0 $Bq \cdot g^{-1}$ set by ISO 6872:2015/Amd 1:2018. 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® NOW, and predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590).

Packaging Validation

The packaging validation was conducted to ensure that the packaging configurations for tBruxZir® NOW are suitable to withstand the distribution environment. Per ASTM D4169-16, BruxZir® NOW and BruxZir® NOW Bridge Block were tested to check resistance against manual handling, vehicle stacking, loose load vibration, vehicle vibration, and concentrated impact. After the test, the shipping containers were visually inspected for any damages. It was determined that the respective packaging for BruxZir® 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® NOW, and predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590).

VIII. CONCLUSION

Based on the technological characteristics and non-clinical test data included in this submission, the subject device, BruxZir® NOW, has been shown to be substantially equivalent to the predicate device, Perfit FS Dental Zirconia Fully Sintered Block (K203590).