January 18, 2022

Prismatik Dentalcraft, Inc.
So Park
Princical Pregulatory Affirs Specialist
2144 Michelson Drive
Irvine, California 96212

Re: K213425
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

Dear So Park:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 17, 2021. Specifically, FDA is updating this SE Letter as an administrative correction. The manufacturing process for the predicate device and subject device were reported incorrectly in the 510(k) Summary.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Michael Adjodha, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6276, michael.adjodha@fda.hhs.gov.

Sincerely,

Michael E. Adjodha -S

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

November 17, 2021

Prismatik Dentalcraft, Inc.
So Park
Princical Pregulatory Affirs Specialist
2144 Michelson Drive
Irvine, California 96212

Re: K213425
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: October 19, 2021
Received: October 21, 2021

Dear So 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)*
K213425

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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.

K213425

510(k) Summary

I. SUBMITTER

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

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

Primary Contact Person: So Hyun Park, Principal Regulatory Affairs Specialist
Secondary Contact Person: Herbert Crane, VP RA/QA

Date Prepared: November 17, 2021

II. DEVICE

Name of Device: BruxZir® Esthetic
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® Shaded (K130924)

IV. DEVICE DESCRIPTION

BruxZir® Esthetic blanks are zirconia milling blanks used for the production of 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 and pre-shaded varieties that can be easily adjusted to match the final shade.

V. 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Attributes		Subject Device	Primary Predicate Device	Comparison
Device Name		BruxZir® Esthetic	BruxZir® Shaded	N/A
510(k)		TBD	K130924	N/A
Regulation		21CFR872.6660	21CFR872.6660	Same
Product Code		EIH	EIH	Same
Classification		Class II	Class II	Same
Manufacturer		Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Intended Use/ 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
Prescription Device		Yes	Yes	Same
Environment of Use		Dental laboratories	Dental laboratories	Same
Design Characteristic	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 and different oxide 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.
	Shades	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, White, BL1,BL3	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,	A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4,	Similar; More final target shades are offered for the

Attributes		Subject Device	Primary Predicate Device	Comparison
		D2, D3, D4, White, BL1,BL3	D2, D3, D4	subject device.
Design Characteristic	Flexural Strength	>800 MPa	>800 MPa	Same
	Density	>6.05 g/cm^3	>6.05 g/cm^3	Same
	Coefficient of Thermal Expansion (CTE/25-500°C)	10-11x10^{-6}/°C	10-11x10^{-6}/°C	Same
	Chemical Solubility	<100 µg/cm2	<100 µg/cm2	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
	Biocompatibility	Biocompatible and non-toxic	Biocompatible and non-toxic	Same
	Sterility	Non-sterile	Non-sterile	Same
	Manufacturing Process	Bi-axial pressing process	Colloidal process	Different manufacturing process

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device, BruxZir® Esthetic, is substantially equivalent in intended use, material, design principles and performance to the primary predicate device, BruxZir® Shaded (K130924). The main components of the subject device, BruxZir® Esthetic, and the predicate device, BruxZir® Shaded (K130924), are substantially equivalent as generic type of material has not been changed and it does not alter the performance specifications of the subject device. The slight differences in overall chemical composition do not affect biocompatibility and performance characteristics.

The fundamental principle of operation of the subject device, BruxZir® Esthetic, and the predicate device, BruxZir® Shaded (K130924), is similar. The difference between the subject device and the predicate device is that the final target shades are achievable without additional coloring steps for the subject device whereas basic staining and glazing techniques are required after sintering in order to achieve the final target shades for the predicate device. 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 substantial equivalence comparison table above outlines and provides the similarities between the subject device, BruxZir® Esthetic, 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 6872:2015/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.

VII. PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

- Mechanical testing for flexural strength, Coefficient of Thermal Expansion (CTE), solubility, radioactivity according to ISO 6872:2015/Amd 1:2018
- Color consistency, translucency, shade match
- Packaging validation
- Biocompatibility

Flexural Strength

The flexural strength was tested on the worst-case group. The average flexural strength of each worst-case block batch tested yielded results above the 800 MPa minimum. The results demonstrate that the product's flexural strength meets the ISO 6872: 2015/Amd 1:2018 requirement to be classified as a Type II, Class 5 ceramic product.

Coefficient of Thermal Expansion (CTE)

Coefficient of Thermal Expansion (CTE) was tested in order to demonstrate compliance with the ISO 6872:2015/Amd 1:2018 requirement. Tests performed on the high and low colorant extreme shades yielded CTE results within the specification range of 10-11 x 10-6/°C and a standard deviation of less than 0.5 x 10-6/°C. The results met the ISO 6872:2015/Amd 1:2018 CTE requirement.

Solubility

Based on the solubility results from similar products that share the same base powder, approximate yttria content, same series of colorants and method of introduction, it was concluded the solubility is below 100 $\mu g/cm^2$ limit, meeting the ISO 6872:2015/Amd 1:2018 requirement.

Radioactivity

Since BruxZir® Esthetic is produced entirely from the raw materials, which have been certified to meet the radioactivity requirement of ISO 6872:2015/Amd 1:2018, and the processes through which those powders are transformed into a finished product inherently do not induce radioactivity, BruxZir® Esthetic meets the radioactivity requirement of ISO 6872:2015/Amd 1:2018 without the need for further testing of the finished product.

Color Consistency

Color consistency within a block, within a batch and between batches was tested. A ΔE of less than 2.0 between two coordinates in the CEILAB color space is considered indicative that two shades being perceptibly identical to one another. With the maximum ΔE calculations being made between the minimum and maximum L*, a*, and b* coordinate constituents within each dataset falling below 2.0, it was concluded that BruxZir® Esthetic conforms to color consistency requirements for and between the batch sizes, block types, and press densities tested. The results of the testing were used to address questions related to substantial equivalence based on differences in

device design between the subject device, BruxZir® Esthetic, and the predicate device, BruxZir® Shaded (K130924).

Translucency

Translucency was tested for every batch as well as each thickness of Zeno block pressed. The results show that BruxZir® Esthetic to be more translucent than the reference product; therefore, demonstrating conformance with acceptance criteria for translucency. The results of the testing were used to address questions related to substantial equivalence based on differences in device design between the subject device, BruxZir® Esthetic, and the predicate device, BruxZir® Shaded (K130924).

Shade Match

Shade match validation was performed on restorations milled and sintered from each block type pressed from each batch. Evaluations of sintered and glazed restorations by qualified reviewers against the VITA Classical and Bleach shade guides concluded that BruxZir Esthetic meets shade match requirements for all batch sizes, restoration types, and press densities tested. The results of the testing were used to address questions related to substantial equivalence based on differences in device design between the subject device, BruxZir® Esthetic, and the predicate device, BruxZir® Shaded (K130924).

Packaging Validation

Packaging validation was also performed for different styles, GL Single Unit and GL Bridge Block, offered for BruxZir® Esthetic. Per ASTM D4169-14, the shipping unit was tested for manual handling, compressive loads, repetitive shocks from vibration, vertical vibration environments, concentrated impacts and secondary manual handling drops. After the tests, the shipping containers were visually inspected for any damages. It was determined that the GL Singe Unit and GL Bridge Block with their respective packaging, 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, and the predicate device, BruxZir® Shaded (K130924).

Biocompatibility

Biological evaluation within a risk management process was performed in accordance with ISO 10993-1:2018 and ISO 14971:2019. Based on the biocompatibility testing results from similar products, it was determined that there is no biocompatibility concern in regards to yttria concentration, colorants, or organic binders. 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, and the predicate device, BruxZir® Shaded (K130924).

VIII. CONCLUSION

BruxZir® Esthetic was evaluated for substantial equivalence using standard and/or comparative testing. Based on technological characteristics and non-clinical test data

included in this submission, BruxZir® Esthetic has been shown to be substantially equivalent to BruxZir® Shaded (K130924).