June 29, 2022

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

Re: K220960
Trade/Device Name: BruxZir Opaque Coloring Liquid
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: March 31, 2022
Received: April 1, 2022

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)*

K220960

Device Name
BruxZir™ Opaque Coloring Liquid

Indications for Use *(Describe)*
BruxZir™ Opaque Coloring Liquid is used for coloring pre-sintered zirconia structures.

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.

K220960
510(k) Summary

I. SUBMITTER

Prismatik Dentalcraft, Inc.
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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: June 24, 2022

II. DEVICE

Name of Device: BruxZir™ Opaque Coloring Liquid
Common Name or Usual Name: Liquid for Dental Zirconia Prosthesis
Classification Name: Porcelain powder for clinical use (21 CFR 872.6660) Regulatory Class: Class II
Product Code: EIH

III. PRIMARY PREDICATE DEVICE

Zirkonzahn COLOUR LIQUID (K190518)

IV. DEVICE DESCRIPTION

BruxZir™ Opaque Coloring Liquid comprises a set of solutions that enhance the esthetic properties of zirconia restorations. The solution is applied to the zirconia restorations before sintering, by dipping the framework into the liquid or by using a metal-free brush. Afterwards, the structure is dried and subsequently sintered at temperatures above 1400°C.

BruxZir™ Opaque Coloring Liquid is available in different colors, Opaq-Lite, Opaq-A, Opaq-C, Opaq, Opaq Plus. The devices are intended to be used solely by dental technicians for fabrication of zirconia restorations for individual dental patients.

V. INDICATIONS FOR USE

BruxZir™ Opaque Coloring Liquid is used for coloring pre-sintered zirconia structures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological Characteristics		Subject Device (TBD)	Predicate Device (K190518)	Comparison
Device Name		BruxZir™ Opaque Coloring Liquid	Zirkonzahn COLOUR LIQUID	N/A
Product Code		EIH	EIH	Same
Manufacturer		Prismatik Dentalcraft, Inc.	ZIRKONZAHN SRL	N/A
Intended Use/ Indications for Use		BruxZir™ Opaque Coloring Liquid is used for coloring pre-sintered zirconia structures.	Zirkonzahn COLOUR LIQUID is used for coloring pre-sintered zirconia structures.	Same except for the device name
Prescription Device		Yes	Yes	Same
Design Characteristics	Chemical Composition	Aqueous solutions of transition and lanthanide metal salts	Aqueous solutions of transition and lanthanide metal salts	Similar
	Biocompatibility	Biocompatible	Biocompatible	Same
	Principles of Operation	Brushing or Dipping Technique	Brushing or Dipping Technique	Same
	Type of Packaging and Volume	Bottle; 175mL	Bottle; 20mL, 50mL, 100mL	Similar
	Shade	Various; Opaq-Lite, Opaq-A, Opaq-C, Opaq, Opaq Plus	Various; A1-D4	Similar
	Sterility	Non-sterile	Non-sterile	Same

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device, BruxZir™ Opaque Coloring Liquid, is substantially equivalent in intended use, material, design principles and performance to the predicate device, Zirkonzahn COLOUR LIQUID (K190518). The intended use/indications for use for both the subject device and the predicate device are the same except for the device name. Both devices are liquids used for coloring pre-sintered zirconia restorations. The fundamental principle of operation of the subject device and the predicate device is same. The subject device and the predicate device are similar in terms of chemical composition as both devices contain transition and lanthanide metals as the major constituents.

The substantial equivalence comparison table above outlines and provides the similarities between the subject device, BruxZir™ Opaque Coloring Liquid, and the predicate device, Zirkonzahn COLOUR LIQUID (K190518). 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 and ISO 10993. And 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 include:

- Mechanical testing for flexural strength and solubility
- Vishal shade evaluation
- Shelf life
- Packaging validation
- Biocompatibility

No clinical data is included in this submission.

Flexural Strength

Flexural strength testing was performed on the zirconia substrate treated with the subject device, BruxZir™ Opaque Coloring Liquid, per ISO 6872:2015/Amd 1:2018. The results of the testing demonstrated that the subject device does not significantly affect the mechanical property of zirconia substrate. 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™ Opaque Coloring Liquid, and the predicate device, Zirkonzahn COLOUR LIQUID (K190518).

Solubility

Chemical solubility was tested on the worst case, which is the zirconia substrate with all 5 shades of the subject device, BruxZir™ Opaque Coloring Liquid applied. It was concluded that the solubility is below 100 µg/cm^2 limit, 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 device design between the subject device, BruxZir™ Opaque Coloring Liquid, and the predicate device, Zirkonzahn COLOUR LIQUID (K190518).

Visual Shade Evaluation

The dental restorations were milled from the zirconia milling blanks with application of the subject device, BruxZir™ Opaque Coloring Liquid. Visual shade evaluations were performed on the sintered and glazed restorations by qualified reviewers against the reference shade guides. It was concluded that BruxZir™ Opaque Coloring Liquid 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

device design between the subject device, BruxZir™ Opaque Coloring Liquid, and the predicate device, Zirkonzahn COLOUR LIQUID (K190518).

Shelf Life

The accelerated aging test was performed per ASTM F1980-16 in order to establish the shelf life of the subject device, BruxZir™ Opaque Coloring Liquid. It was concluded that the shelf life of BruxZir™ Opaque Coloring Liquid is 2 years. The results of the testing were used to address questions related to substantial equivalence based on differences in shelf life between the subject device, BruxZir™ Opaque Coloring Liquid, and the predicate device, Zirkonzahn COLOUR LIQUID (K190518).

Packaging Validation

Packaging validation was performed on the subject device, BruxZir™ Opaque Coloring Liquid. Per ASTM D4169-16, the shipping unit was tested for manual handling drops, vehicle stacking, loose load vibration, low pressure hazard, vehicle vibration and concentrated impact. Following distribution simulation testing, the packaging contents were visually inspected for signs of damages, or leaks. Visual examination of the parts did not reveal any damage of the packaged contents and any leaks of the coloring liquids and revealed that the seal of the bottles was intact. The results of the testing were used to address questions related to substantial equivalence based on differences in packaging configuration between the subject device, BruxZir™ Opaque Coloring Liquid, and the predicate device, Zirkonzahn COLOUR LIQUID (K190518).

Biocompatibility

The subject device, BruxZir™ Opaque Coloring Liquid, was tested in accordance with ISO 10993-1. Per the biological evaluation, BruxZir™ Opaque Coloring Liquid was tested for Cytotoxicity (ISO 10993-5:2009), Sensitization (ISO 10993-10:2010) and Oral Mucosal Irritation (ISO 10993-10:2010) to meet the biocompatibility requirements. Based on the biocompatibility testing results, it was determined that there is no biocompatibility concern for the subject device. 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™ Opaque Coloring Liquid, and the predicate device, Zirkonzahn COLOUR LIQUID (K190518).

VIII. CONCLUSION

Based on the technological characteristics and non-clinical test data included in this submission, the subject device, BruxZir™ Opaque Coloring Liquid, has been shown to be substantially equivalent to the primary predicate device, Zirkonzahn COLOUR LIQUID (K190518).