June 9, 2023

Prismatik Dentalcraft, Inc.
Nina Chiang
Regulatory Affairs Specialist
2144 Michelson Drive
Irvine, California 92612

Re: K231347
Trade/Device Name: BruxZir™ TintEFX Coloring Liquid
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 4, 2023
Received: May 9, 2023

Dear Nina Chiang:

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,

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

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)*

K231347

Device Name
BruxZir™ TintEFX Coloring Liquid

Indications for Use *(Describe)*
BruxZir™ TintEFX 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.

K231347

510(k) Summary

I. SUBMITTER

Prismatik Dentalcraft, Inc.
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Irvine, CA 92612, USA

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Date Prepared: May 04, 2023

II. DEVICE

Name of Device: BruxZir™ TintEFX 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. PREDICATE DEVICE

BruxZir™ Opaque Coloring Liquid (K220960)

IV. DEVICE DESCRIPTION

BruxZir™ TintEFX 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™ TintEFX Coloring Liquid is available in 14 different colors, Brown, Green, Blue, Pink, Orange, Purple, Grey, Yellow, G00, G0, G1, G3, G4, and G5. The devices can be used on the gingival part, body part, and/or incisal part of dental restoration to provide esthetic properties and mimic nature tooth color. 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™ TintEFX Coloring Liquid is used for coloring pre-sintered zirconia structures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological Characteristics		Subject Device (K231347)	Predicate Device (K220960)	Comparison
Device Name		BruxZir™ TintEFX Coloring Liquid	BruxZir™ Opaque Coloring Liquid	N/A
Product Code		EIH	EIH	Same
Manufacturer		Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Intended Use/ Indications for Use		BruxZir™ TintEFX Coloring Liquid is used for coloring pre-sintered zirconia structures.	BruxZir™ Opaque Coloring Liquid is used for coloring pre-sintered zirconia structures.	Same
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; additional transition and lanthanide metals and nitric acid for the subject device
	Biocompatibility	Biocompatible	Biocompatible	Same
	Principle of Operation	Brushing or Dipping Technique	Brushing or Dipping Technique	Same
	Type of Packaging and Volume	Bottle; 175mL (150mL Volume)	Bottle; 175mL (150mL Volume)	Same
	Shades	Various; Brown, Green, Blue, Pink, Orange, Purple, Grey, Yellow, G00, G0, G1, G3, G4, and G5	Various; Opaq-Lite, Opaq-A, Opaq-C, Opaq, Opaq Plus	Different
	Flexural Strength	>800 MPa	>800 MPa	Same
	Chemical Solubility	<100 µg/cm^2	<100 µg/cm^2	Same
	Visual Shade Evaluation	Pass	Pass	Same
	Sterility	Non-sterile	Non-sterile	Same

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device, BruxZir™ TintEFX Coloring Liquid, is substantially equivalent in intended use, material, design principles and performance to the predicate device, BruxZir™ Opaque Coloring Liquid (K220960). 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 the same. The subject device and the predicate device are similar in terms of chemical composition as both devices contain transition and lanthanide metal salts as the major constituents. The differences in terms of chemical composition does not raise any new concerns of safety and effectiveness of the subject device as the performance testing results of the subject device support that the subject device is substantially equivalent to the predicate device.

The substantial equivalence comparison table above outlines and provides the similarities between the subject device, BruxZir™ TintEFX Coloring Liquid, and the predicate device, BruxZir™ Opaque Coloring Liquid (K220960). 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.

VII. PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

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

No clinical data is included in this submission.

Flexural Strength

Flexural strength testing was tested on the zirconia substrate treated with the worst case of the subject device, BruxZir™ TintEFX Coloring Liquid, per ISO 6872:2015/Amd 1:2018. The results demonstrate that the subject device applied to the zirconia substrate satisfies the minimum mechanical properties of zirconia required for Type II, Class 5 per ISO 6872:2015/Amd 1:2018. 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™ TintEFX Coloring Liquid, and the predicate device, BruxZir™ Opaque Coloring Liquid (K220960).

Chemical Solubility

Chemical solubility was tested on the worst case. It was concluded that the solubility is below the 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™ TintEFX Coloring Liquid, and the predicate device, BruxZir™ Opaque Coloring Liquid (K220960).

Visual Shade Evaluation

The dental restorations were milled from zirconia milling blanks with application of the subject device, BruxZir™ TintEFX Coloring Liquid. Visual shade evaluations

were performed on the sintered and glazed restorations by qualified reviewers against reference shade guides. It was concluded that BruxZir™ TintEFX 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™ TintEFX Coloring Liquid, and the predicate device, BruxZir™ Opaque Coloring Liquid (K220960).

Shelf Life

The accelerated aging test was performed per ASTM F1980-21 to establish the shelf life of the subject device, BruxZir™ TintEFX Coloring Liquid. It was concluded that the shelf life of BruxZir™ TintEFX Coloring Liquid is 0.5 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™ TintEFX Coloring Liquid, and the predicate device, BruxZir™ Opaque Coloring Liquid (K220960).

Packaging Validation

Packaging configurations were evaluated to ensure that it is suitable to withstand the distribution environment such that the device packaged in a bottle can be sent to a customer undamaged. The subject device, BruxZir™ TintEFX Coloring Liquid, uses the same packaging materials and packaging configurations as the predicate device, BruxZir™ Opaque Coloring Liquid (K220960). The results of the previous packaging validation were used to address questions related to substantial equivalence based on differences in packaging configuration between the subject device, BruxZir™ TintEFX Coloring Liquid, and the predicate device, BruxZir™ Opaque Coloring Liquid (K220960).

Biocompatibility

The subject device, BruxZir™ TintEFX Coloring Liquid, was tested in accordance with ISO 10993-1. Per the biological evaluation, BruxZir™ TintEFX Coloring Liquid was tested for Cytotoxicity (ISO 10993-5:2009), Skin Sensitization (ISO 10993-10:2021), and Oral Mucosal Irritation (ISO 10993-10:2021) 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™ TintEFX Coloring Liquid, and the predicate device, BruxZir™ Opaque Coloring Liquid (K220960).

VIII. CONCLUSION

Based on the technological characteristics and non-clinical test data included in this submission, BruxZir™ TintEFX Coloring Liquid has been shown to be substantially equivalent to the predicate device, BruxZir™ Opaque Coloring Liquid (K220960).