November 22, 2019

Prismatik Dentalcraft, Inc.
Mythili Reguraman
RA/QA Associate
2212 Dupont Dr.
Irvine, California 92612

Re: K191903
Trade/Device Name: BruxZir GT (Gum Tissue) Color™
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: August 19, 2019
Received: August 26, 2019

Dear Mythili Reguraman:

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 Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191903

Device Name
BruxZir GT (Gum Tissue) Color™

Indications for Use *(Describe)*
BruxZir GT (Gum Tissue) Color™ is indicated for metal free single posterior crowns, multiple unit anterior crowns/ bridges including full and partial arches, bonded restorations.

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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510(k) Summary

A. SUBMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	2212 Dupont Dr. Irvine, CA 92612
Company Phone:	(949) 440-2678
Company Fax:	(949) 553-0924
Establishment Registration Number:	3011649314
Primary Contact Person:	Mythili Reguraman RA/QA Associate
Secondary Contact Person:	Herbert Schoenhoefer RA/QA Director (949) 440-2632 herbert.schoenhoefer@glidewelldental.com
Date Summary Prepared:	November 20th, 2019

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	BruxZir GT (Gum Tissue) Color™
Common Name:	Gum Tissue colorant
Classification Name:	Porcelain powder for clinical use
Regulation Number:	21 CFR 872.6660
Product Code:	EIH
Device Class:	2
Review Panel:	Dental

C. IDENTIFICATION OF PREDICATE DEVICE

Predicate: Zirkonzahn Color Liquid Prettau Aquarell Tissue B (K061851)

D. DEVICE DESCRIPTION

BruxZir GT (Gum Tissue) Color™ is a coloring solution for the gum tissue (gingival) area of full and partial-arch dental restorations. The product can also be used for crowns and bridges when restoration of the gingival area is included. It provides shade consistency, aesthetics and efficiency when preparing a zirconia restoration. The solution is to be applied to green stage restoration before sintering. The BruxZir GT (Gum Tissue) Color™ comes in a 150 mL bottle.

E. INDICATIONS FOR USE

BruxZir GT (Gum Tissue) Color™ is indicated for metal-free single posterior crowns, multiple-unit anterior crowns/bridges including full and partial arches, bonded restorations.

F. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Refer to the Comparison Table below showing similarities and differences between the predicate device and subject device.

Table 8-1 – Comparison between Predicate device and Subject device

Feature	Subject Device	Predicate Device	Comparison
Trade Name	BruxZir GT (Gum Tissue) Color™	Zirkonzahn Color Liquid Prettau Aquarell Tissue B	
510(k)	K191903	K061851	
Regulation	21 CFR 872.6660	21 CFR 872.6660	Same
Product Code	EIH	EIH	Same
Classification	II	II	Same
GMDN Code	17844	17844	Same
GMDN Preferred Term	Dental Articulation Liquid	Dental Articulation Liquid	Same
Indications for Use	Metal free single posterior crowns, multiple unit anterior crowns/bridges including full and	Metal free single posterior crowns, multiple unit anterior crowns/bridges, inlays,	Similar

	partial arches, bonded restorations	onlays, bonded dental restorations	
Feature	**Subject Device**	**Predicate Device**	**Comparison**
Use of device	Applied to green stage products prior to sintering	Applied to green stage products prior to sintering	Same
Prescription Device	Yes	Yes	Same
Contraindication	None	None	Same
Environment of Use	Dental laboratories	Dental laboratories	Same
Design			
Shade	Pink	Pink	Same
Flexural Strength of color treated Zirconia	≥ 800 MPa	≥ 800 MPa	Same
Fracture Toughness of color treated Zirconia	≥5.0 MPa · $m^{1/2}$	≥5.0 MPa · $m^{1/2}$	Same
Solubility of color treated Zirconia	≤100 µg/cm^2	≤100 µg/cm^2	Same
Purpose	Inorganic pigment used to produce the color of a sintered zirconia product and is uniformly dispersed throughout the dental restoration.	Inorganic pigment used to produce the color of a sintered zirconia product and is uniformly dispersed throughout the dental restoration.	Same
Materials			
	BruxZir GT (Gum Tissue) Color™ is composed of a mixture of metal salts and bio-pigments.	Colour Liquid Prettau Aquarell Tissue B is composed of a proprietary mixture of metal salts and bio-pigments.	Similar
Biocompatibility	Biocompatible and non -toxic	Biocompatible and non-toxic	Same
Sterility	Provided Non-Sterile	Provided Non- Sterile	Same

The indication for use of Zirkonzahn states that it can be used for single posterior crowns, multiple unit anterior crowns/bridges, inlays, onlays and bonded restorations. For Bruxzir GT (Gum Tissue) Color™ solution, the indications for use is similar and can be used on single posterior crowns, multiple unit anterior crowns/bridges including full and partial arches as well as bonded restorations. The 510(k) for Zirkonzhan Color Liquid Prettau Aquarell Tissue B (K061851) also covered Zirkonzahn Ice, therefore their indications for use included inlays and onlays. The minor difference in use is justified by the fact that BruxZir GT (Gum Tissue) Color™ is intended for the gingival areas and therefore would not be used for inlays or onlays since these restorations do not include the gingival area.

Zirkonzahn Color Liquid Prettau Aquarell Tissue B (K061851) coloring solution contains red colorants while BruxZir GT (Gum Tissue) Color™ solution uses green food coloring solution. The sintering process exposes the food coloring components to temperatures much higher than their decomposition temperature for extended times, all of the components will completely decompose.

Although the amount of iron present in the predicate device, < 0.1%, is greater than that of the subject device, the amounts of iron does not affect substantial equivalence. Moreover, the subject device has passed full biocompatibility testing.

In summary, the main components of the subject device and its predicate are substantially equivalent, and the slight differences in overall chemical composition does not affect the substantial equivalence of the subject when compared to the predicate device.

G. PERFORMANCE DATA

Prismatik Dentalcraft performed various non-clinical tests and a risk analysis was also conducted to comply with ISO 14971:2012. The test results for the penetration of BruxZir GT (Gum Tissue) Color™ solution, solubility (ISO 6872:2015), the flexural strength (ISO 6872:2015) and fracture toughness (ISO 6872:2015) indicate that BruxZir GT (Gum Tisue) Color™ is comparable to the predicate device.

In addition, BruxZir GT (Gum Tissue) Color™ has also been tested for Cytotoxicity (ISO 10993-5:2009), Sensitization (ISO 10993-10:2010) and Irritation (ISO 10993-10:2010) to meet the biocompatibility requirement and the results are as follows:

- The Cytotoxicity Report shows that there was no evidence of causing cell lysis or toxicity.
- The Sensitization Report shows that there was no reaction on the tested subject.
- The Irritation Report shows that the test article was considered a nonirritant.

H. CONCLUSION

The documentation submitted in this premarket notification demonstrates that the BruxZir GT (Gum Tissue) Color™ is substantially equivalent to the predicate device.