June 10, 2020

Prismatik Dentalcraft, Inc.
So Hyun Park
Sr. Regulatory Affairs Specialist
2212 Dupont Drive, Suite P
Irvine, California 92612

Re: K200131
Trade/Device Name: BruxZir Steel™
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 15, 2020
Received: May 18, 2020

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 Srinivas “Nandu” Nandkumar, Ph.D.
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)*

K200131

Device Name

BruxZir Steel™

Indications for Use *(Describe)*

BruxZir Steel™ can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading and to produce a strong prosthesis with a porcelain-like finish. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.

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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K200131

510(k) Summary

A. SUBMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	2212 Dupont Drive, Suite P Irvine, CA 92612
Company Phone:	+1 949-863-5479
Company Fax:	+1 949-553-0924
Establishment Registration Number:	3011649314
Primary Contact Person:	So Hyun Park Sr. Regulatory Affairs Specialist So.park@glidewelldental.com
Secondary Contact Person:	Herbert Schoenhoefer RA/QA Director Herbert.Schoenhoefer@glidewelldental.com +1 949-440-2632
Date Summary Prepared:	June 9, 2020

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	BruxZir Steel™
Common Name:	Dental restorative material
Classification Name:	Porcelain powder for clinical use
Regulation Number:	21 CFR 872.6660
Product Code:	EIH
Device Class:	Class II
Classification Panel	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

C. IDENTIFICATION OF PREDICATE DEVICE

Primary Predicate: DMAX Coloring Liquid (K173769)

Reference Device: ZirBlank®-FS (K070045)

D. DEVICE DESCRIPTION

BruxZir Steel™ is a Coloring Liquid used to produce a natural whitening effect while increasing the flexural strength and fracture toughness of 4.6 - 4.9 mol% yttria-stabilized zirconia (YSZ). The product increases the shade esthetics of the restoration while maintaining the translucency. Application of the product to the zirconia substrate prior to sintering provides enhanced shade characteristics and improved flexural strength and fracture toughness.

E. INDICATIONS FOR USE

BruxZir Steel™ can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading and to produce a strong prosthesis with a porcelain-like finish. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.

F. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device, BruxZir Steel™, is substantially equivalent to the primary predicate device, DMAX Coloring Liquid, (K173769) in intended use, material, design and performance.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate. Both the subject device and the primary predicate device can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading and intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients. Slight difference in the subject device and primary predicate device Indications for Use does not affect the intended use and is supported by the reference device, ZirBlank®-FS (K070045). The subject device and the reference device include tantalum. The performance testing data also supports a new indication for use by showing that the subject device increases the flexural strength and fracture toughness of zirconia. Both IFUS express equivalent intended use to facilitate fabrication of zirconium dioxide restorations for individual dental patients, and indication for a strong prosthesis with a porcelain-like finish is expressed equivalently using different specific wording.

The differences between the predicate device and the subject device in terms of chemical composition are the presence of tantalum(V) oxide, less amount of silicon dioxide, and absence of sodium in the subject device. After sintering, the remaining tantalum pentoxide, which is incorporated into the zirconia substrate, is proven biocompatible. Silicon dioxide in the predicate device is a whitening agent, which makes the zirconia restoration whiter. The absence of sodium in the subject device does not affect the intended use.

Although the base solutions for BruxZir Steel™ and DMAX Coloring Liquid are not identical (i.e. alcohol-based solution and water-based solution respectively), the difference does not affect the intended use, performance characteristics, or principle of operation.

The subject device and the reference device employ tantalum prior to sintering the zirconia substrate. Substantial equivalence of the subject device components to the reference device in terms of biocompatibility is supported by the fact that tantalum has been acknowledged as being biocompatible for use in dental applications. Nonetheless, biocompatibility testing was performed on the subject device and the device was proven biocompatible.

The comparison table below (Table 7-1) outlines and provides the similarities and differences among the subject device, primary predicate device and reference device.

In summary, the subject device is substantially equivalent to the predicate device.

G. PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

- Biocompatibility according to ISO 10993-5:2009 and ISO 10993-10:2010
  - 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.

- Mechanical testing for flexural strength, fracture toughness, solubility according to ISO 6872:2015

- L* value obtained from L*a*b* color space testing after applying BruxZir Steel™ onto zirconia for dental restoration according to ISO 11664-4:2019.

Biological evaluation within a risk management process was performed in accordance with ISO 10993-1:2018 and EN ISO 14971:2012.
No clinical data were included in this submission.

H. CONCLUSION

The documentation submitted in this premarket notification demonstrates that the BruxZir Steel™ is substantially equivalent to the predicate device.

Table 7-1 – Comparison between predicate device and subject device

Feature	Subject Device	Primary Predicate	Reference Device
Device Name	BruxZir Steel™	DMAX Coloring Liquid	ZirBlank®-FS
510(k)	K200131	K173769	K070045
Regulation	21 CFR 872.6660	21 CFR 872.6660	21 CFR 872.6660
Product Code	EIH	EIH	EIH
Classification	II	II	II
Indications for Use	BruxZir Steel™ can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading and to produce a strong prosthesis with a porcelain-like finish. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.	DMAX coloring liquid can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.	Intended for use in preparation of crowns, facings, inlays and onlays – to produce a hard prosthesis with a porcelain-like finish. Frequently used with porcelain overlay for translucence and related effects. For fabricating copings and frameworks for inlays, onlays, veneers, crowns, anterior and posterior bridge restorations. Intended to restore carious lesions or structural defects in teeth. It is intended for use in cavities Classes I, II, and V (inlays and onlays) and as a restorative material intended for veneers, crowns and bridges.

Feature	Subject Device	Primary Predicate	Reference Device
Contraindication	Do not use on 3Y zirconia.	None	None
Prescription Device	Yes	Yes	Yes
Environment of Use	Dental laboratories	Dental laboratories	Dental laboratories
Design	Alcohol-based Tantalum Ethoxide solution with burn-out at 100% during sintering, which is incorporated into a zirconia substrate as sub-micron sized Tantalum Pentoxide	Water-based with inorganic pigments applied to zirconium dioxide dental restorative material before sintering	Tantalum Pentoxide added to a yttrium oxide-stabilized zirconia (Y-TZP)
Principle of Operation	Brush zirconia ceramic with coloring liquid before sintering	Brush or immerse zirconia ceramic with coloring liquid before sintering	Not Applicable
Shade	1 color	45 colors	Not Applicable
Storage Conditions	Store at 22-25°C	Store at 2-28°C	Store at room temperature
Flexural Strength of Tantalum Treated Zirconia	1 GPa	Not Applicable	600 MPa
Fracture Toughness of Tantalum Treated Zirconia	≥ 5.0 MPa $\cdot$ $m^{1/2}$	Not Applicable	≥ 5.0 MPa $\cdot$ $m^{1/2}$

Feature	Subject Device	Primary Predicate	Reference Device
Solubility of Tantalum Treated Zirconia	≤100 µg/cm^2	≤100 µg/cm^2	≤100 µg/cm^2
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Sterility	Non-Sterile	Non-Sterile	Non-Sterile