



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 15, 2014

Prismatik Dentalcraft, Inc.
Mr. Armin Zehtabchi
Senior RA Specialist
2212 Dupont Drive, Suite P
Irvine, CA 92612

Re: K143330
Trade/Device Name: BruxZir™ Anterior
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH
Dated: November 24, 2014
Received: November 26, 2014

Dear Mr. Zehtabchi:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Susan Runna DDS, MA". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

TBD K143330

Device Name

BruxxZi™ Anterior

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"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."

007_510 (K) Summary-807.92(c)

This 510 (k) summary is being submitted in accordance with the requirements of SMDA of 1990 and 21 CFR 807.92.

A. SUBMITTER INFORMATION

Company Name: Prismatik Dentalcraft, Inc.
Company Address: 2212 Dupont Dr., Suite P,
Irvine, CA 92612
Company Phone: 949-225-1269
Company FAX: 949-553-0924
Facility Registration Number: 3005477956
Primary Contact Person: Armin Zehtabchi, (949) 225-1234
Senior RA Specialist
Secondary Contact Person Marilyn Pourazar, (949) 225-1269
Senior Director, RA/QA
Date Summary Prepared: November 19, 2014

B. DEVICE IDENTIFICATION

Trade/Proprietary Name: BruxZir™ Anterior
21 CFR Reference: 21 CFR 872.6660
21 CFR Common Name: Porcelain powder for clinical use
Classification: Class II, EIH
Panel: Dental

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name: BruxZir™ Shaded-K130924

D. PROPOSED DEVICE DESCRIPTION

BruxZir™ Anterior Blanks are zirconia milling blanks that are used for the production of highly esthetic full-contour zirconia dental restorations. The high esthetics of BruxZir™ Anterior makes it ideal for use in the anterior region. The manufactured full contour dental restorations are made utilizing the CAD/CAM system for design and manufacture. The designed and manufactured full-contour dental restorations are then sintered at a high temperature. BruxZir™ Anterior White will have to undergo color alteration prior to sintering (colorants not provided by Prismatik). No color needs to be added to preshaded BruxZir™ Anterior Blanks (150, 250, 350, 450, 550) before sintering. Basic staining and glazing techniques need to be used after sintering to achieve the desired shade. The sintered material exhibits maximum strength and translucent pearlescence.

E. 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.

F. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The comparison table below outlines and provides the similarities and the substantial equivalency of the predicate device, BruxZir™ Shaded-K130924 (cleared by FDA on 05/16/2013) and the proposed BruxZir™ Anterior. Prismatik believes that the comparative data presented in the preceding paragraphs demonstrate that proposed BruxZir™ Anterior is essentially the same as currently marketed devices for the same indications for use, and supports our claim of substantial equivalence to predicate Class II devices under the classification of porcelain powder for clinical use (21 CFR 872.6660) that have previously been found to be substantially equivalent. Any differences between the proposed device, BruxZir™ Anterior, and the predicate device do not introduce any new issues of safety or effectiveness. Both the proposed device and the predicate device consist of general porcelain powder material and have the same intended use.

Table 1 – Comparison between Predicate and Proposed Device

	Predicate Devices	Proposed Device
	BruxZir™ Shaded (K130924)	BruxZir™ Anterior
Classification of Ceramic	Type II, Class 6	Same
Shapes / Sizes	Standard & "R", "Z" Type, "DD", "ZZ", "ZZ" Notch, "N" Style Blocks, "L" Style	Standard & "R", "Z" Type, "DD", "ZZ", "ZZ" Notch,
Shades	Base Shades (4)	Base Shades (5)
Final Vita Shades	A1, B1, C1, A2, A3, B2, A3.5, B3, C2, D2, D3, D4, A4, B4, C3, C4	Same
Material	Tosoh Powder	Same
Additional Material	Coloring Liquids	Same
Flexural Strength	Meets requirements, per ISO 6872	Same
Coefficient of Thermal Expansion (CTE) / (25-500°C)	$11 \times 10^{-6}/K$	Same
Density	6.05 g/cm^3	Same
Biocompatibility	Biocompatible & Non-toxic	Same
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.	Same

G. SUMMARY OF NON-CLINICAL TESTING (PERFORMANCE DATA)

Non-clinical test data was used to support the substantial equivalency. The functionality of the BruxZir™ Anterior Blocks as well as their conformance to design input was further determined by performance testing (flexural strength, translucency, shades/color consistency and the coefficient of thermal expansion (CTE)). In addition, the proposed device, BruxZir™ Anterior blocks, has been tested for biocompatibility.

H. CONCLUSION FROM THE NON-CLINICAL TESTING (PERFORMANCE DATA)

The proposed device, BruxZir™ Anterior Blocks, has the same performance specifications, fundamental scientific technology and intended use as that of the predicate device, BruxZir™ Shaded-K130924 (cleared by FDA on 05/16/2013). The changes to the device do not raise any new questions regarding safety or efficacy. The performance data and a declaration of conformity with design controls support a determination of continuing substantial equivalence of the proposed device to the predicate device.