PRISMATIK
DENTALCRAFT, INC.

K130924

MAY 16 2013

006-510 (K) Summary-807.92(c)

This 510 (K) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

A. SUBMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	2212 Dupont Dr., Suite IJK, 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:	April 12, 2013

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	BruxZir® Shaded
21 CFR Reference:	21 CFR 872.6660
21 CFR Common Name:	Porcelain powder for clinical use
Classification:	Class II
Panel:	Dental

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:	Prismatik™ Clinical Zirconia (Prismatik™ CZ)-K060104

D. DEVICE DESCRIPTION

BruxZir® Shaded Blanks are used for the production of full-contour zirconia and zirconia-based substructures for crowns and bridges. Four (4) thicknesses (12 mm, 15 mm, 20 mm, 25 mm) and four (4) shades (100, 200, 300, 400) are available for milling into BruxZir full-contour crowns and substructures.

E. DEVICE MANUFACTURING PROCESS:

BruxZir® Shaded are manufactured using a colloidal processing without mechanical pressing or the use of organic binders which lead to decreased esthetics. Other dental Zirconia materials on the market today use organic binders to hold the powder together during the high pressure pressing to form the milling blanks. Conversely, BruxZir®'s colloidal process utilizes vacuum slip casting to form the blocks. This process creates a block with superior microstructure and homogeneity when compared to pressed blocks.

Vacuum slip casting is a ceramic forming technique which uses ceramic slip and a porous mold made from Plaster of Paris. The ceramic powder consolidates and accumulates on the top of the porous mold while the water is absorbed into it, thus forming a high density green state block. One of the several advantages for the colloidal process employed in the creation of BruxZir® products is that smaller particles dispersed using TMAOH and are compacted homogenously through the colloidal process. This results in a material that has a higher translucency value. This allows the end product to have a closer appearance to a natural tooth.

The BruxZir® Shaded block is available in different shapes such as Standard, D Blocks and Z Blocks. The sizes are: 12mm, 15mm, 20mm, 25mm, and 30mm. The drawings of different blocks are provided in this submission.

F. 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.

G. SUBSTANTIAL EQUIVALENCE

The following comparison chart outlines and provides the similarities and the substantial equivalency of the Prismatik™ Clinical Zirconia (Prismatik™ CZ)-K060104 and the BruxZir® Shaded. Prismatik believes that the comparative data presented in the preceding paragraphs, demonstrate that BruxZir® Shaded is essentially the same as currently marketed devices for the same indication 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, and that any differences between the BruxZir® Shaded and the predicate device do not introduce any new issues of safety or effectiveness. Both the modified device and the predicate device consist of general porcelain powder material (Product Code:

EIH). Both the predicate device and the modified device have the same intended use.

Comparison of Predicate Devices

Elements of Comparison	Prismatik™ Clinical Zirconia (Prismatik™ CZ)-K060104 (predicate device)	Prismatik BruxZir® Shaded (modified device)
General Material	Powder, porcelain	Same
Raw Material Supplier	Tosoh Corporation	Same
Indications	The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location	Same
Biocompatibility	Yes	Same
Sterility	Non-sterile	Same
Labeling of the Intended Use	Same	Same A minor change to the name from *Prismatik™ Clinical Zirconia (Prismatik™ CZ to BruxZir® Shaded*
Design	Various Sizes and Thicknesses 12mm, 15mm, 20mm, 25mm, and 30mm	Same
Performance	Performance and technological characteristics have been previously cleared for market (K060104)	Same

H. NON-CLINICAL TESTING

Applicable testing was performed in accordance with the Design Verification Plan including a Risk Analysis addressing the impact of changes to the device. The test results indicate the Prismatik BruxZir® Shaded Blank is comparable to the predicate device.

I. BIOCOMPATIBILITY

Non-clinical test data was used to support the substantial equivalency.
The functionality of the BruxZir® Shaded Blocks as well as their conformance to design input was further determined by laboratory testing. BruxZir® Shaded has been tested for Cytotoxicity (ISO 10993-5), Sensitization (ISO 10993-10), and Irritation (ISO 10993-10) tests to meet the biocompatibility requirement and the reports are as follow:

- The Cytotoxicity Report shows that there was no reaction on any of the cells.
- The Sensitization Report shows that there was no reaction on the tested subject.
- The Irritation Report shows that there was no erythema or edema on the test subject.

Test Description	**Results**
Cytotoxicity Study using the IX MEM extraction method at 37°C	Pass
ISO Intracutaneous Study, Extract 0.9% sodium chloride USP solution (SC) and sesame oil, NF (SO)	Pass
Irritation and Skin Sensitization Study, Extract 0.9% sodium chloride USP and sesame oil, NF (SO)	Pass

The BruxZir® product is manufactured from TZ-Series of zirconia powders free of organic binder material which exhibits superior mechanical properties, and it is a great material for dental restorations for the following four (4) physical properties such as high flexural strength, high fracture toughness (K1C), great resistance to thermal shock and most innovative, is the color and translucency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2013

Mr. Armin Zehtabchi
Senior Regulatory Affairs Specialist
Prismatik Dentalcraft, Incorporated
2212 Dupont Drive, Suite IJK
IRVINE CA 92612

Re: K130924
Trade/Device Name: BruxZir® Shaded
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: April 12, 2013
Received: April 16, 2013

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,

Kwame O. Ulmer -S FDA for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
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Enclosure

PRISMATIK
DENTALCRAFT, INC.

005-Indications for Use Statement

510 (K) Number (if known): K130924

Device Name: BruxZir® Shaded

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.

Prescription Use: Yes ☒ **No** ☐
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use: Yes ☐ **No** ☒
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=13000879950
Date: 2013.05.08 12:36:47 -04'00'

Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130924