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

Prismatik Dentalcraft, Inc.
Maria Wagner
Senior RA
2212 Dupont Drive, Suite P
Irvine, California 92612

July15, 2016

Re: K160425
Trade/Device Name: CAD/CAMouflage Milling Block
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: June 15, 2016
Received: June 16, 2016

Dear Ms. Wagner:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160425

Device Name
CAD/CAMouflage Milling Block

Indications for Use *(Describe)*

CAD/CAMouflage Milling Block is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The CAD/CAMouflage Milling Block is made for fabricating temporary and permanent restorations such as inlays, onlays, veneers and full crown 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.

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PRISMATIK DENTALCRAFT, INC.

510(k) Summary

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

A. SUBMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	2212 Dupont Dr., Suite P, Irvine, CA 92612
Company Phone:	949-440-2636
Company FAX:	949-553-0924
Facility Registration Number:	3005477956
Primary Contact Person:	Maria E Wagner, (949) 440-2636 Senior Specialist, Regulatory Affairs
Secondary Contact Person	Lisa Maloney, (949) 440-2631 Sr. Manager, Regulatory Affairs
Date Summary Prepared:	July 14, 2016

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	CAD/CAMouflage Milling Block
Reference:	21 CFR 872.3690
Classification Name:	Material, Tooth Shade Resin
Classification:	Class II
Product Code:	EBF, EBG
Panel:	Dental

C. **IDENTIFICATION OF PREDICATE DEVICE**

Trade/Proprietary Name:	CAD/CAMouflage Milling Block
Primary Device:	CERASMART™-K133824
Reference Device:	Camouflage Nanohybrid Composite-K133850

D. **DEVICE DESCRIPTION**

The CAD/CAMouflage Milling Block is a nanohybrid composite material that is designed as an indirect restorative for both anterior and posterior restorations including occlusal surfaces. The CAD/CAMouflage Milling Block is made for fabricating indirect restorations such as inlays, onlays, veneers and full crown restorations, including crowns. The mandrel is solely to aid in the manipulation of the material during processing (grinding, shaping, cutting, etc.). It is removed prior to the material (subject device) being put into final placement. As such, there are no implications for device performance or safety, since it is removed, and it has no patient contact.

E. **INDICATIONS FOR USE**

CAD/CAMouflage Milling Block is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The CAD/CAMouflage Milling Block is made for fabricating temporary and permanent restorations such as inlays, onlays, veneers and full crown restorations.

F. **SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE PROPOSED DEVICE AND THE PREDICATE DEVICES**

Prismatik utilized the **FDA's Guidance for Industry and FDA Staff - Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions** for comparing its CAD/CAMouflage Milling Blocks with the Primary Device: CERASMART™ and reference device: Prismatik's Camouflage Nanohybrid Composite. The following comparison table of the technological characteristics of the proposed device, the predicate and reference devices outlines and provides the similarities and the substantial equivalency of the CAD/CAMouflage Milling Blocks and the cited predicate and reference devices.

Comparison of Technological Characteristics of the Proposed Device and the Predicate Devices

Attributes	Reference Device: Camouflage NanoHybrid Composite 510(k)-K133850 Prismatik Dentalcraft, Inc.	Predicate Device: Cerasmart 510(k)-K133824 GC AMERICA, INC.	Proposed Device: CAD/CAMouflage Milling Blocks Prismatik Dentalcraft, Inc.	Similarities & Differences
FDA Classification Name	Tooth shade resin material	Tooth shade resin material	Tooth shade resin material	Same
FDA Product Code	EBF	EBF, EBG	EBF, EBG	Similar to Predicate Device Same as Reference Device
FDA Device Classification	Class II per 21 CFR 872.3690	Class II per 21 CFR 872.3690	Class II per 21 CFR 872.3690	Same
Chemical Composition	Composite Restorative Material	Composite Restorative Material	Composite Restorative Material	Similar to Predicate Device; Similar to Reference Device
Intended Use	Intended to restore carious lesions or structural defects in teeth	The product is indicated for inlays, onlays, veneers and full crown restorations, including crowns on implants	Intended to restore carious lesions or structural defects in teeth	Same as Predicate Device; Similar to Reference Device
Indications	Cavity classes I, II, III, IV, V and VI in anterior and posterior teeth; used as direct restorative material; can use for fabrication of inlays and onlays	Indicated for inlays, onlays, veneers and full crown restorations, including crowns on implants	CAD/CAMouflage Milling Block is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The CAD/CAMouflage Milling Block is made for fabricating temporary and permanent restorations such as inlays, onlays, veneers and full crown restorations.	Same as Predicate Device; Similar to Reference Device
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Same
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same
Single or Multiple Use	Single Patient, multiple use	Single Patient, multiple use	Single Patient, multiple use	Same

Prescription/OCT Use	Prescription	Prescription	Prescription	Same
Substantial Equivalence	The proposed device has comparable indications, intended use, biocompatibility, chemical composition, mechanical and chromatic properties to the predicate device, and has similar characteristics to the reference device. We consider the proposed device to be substantially equivalent to the predicate device, and believe any differences between the proposed and predicate & reference devices will not pose new equvalency concerns.			

G. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The above comparison table of the technological characteristics of the proposed device and the predicate and reference devices was provided for the substantial equivalency of the CAD/CAMouflage Milling Blocks with the Primary Device: CERASMART™-K133824 and the referenced device: Prismatik's Camouflage Nanohybrid Composite-K133850, and reference device: Prismatik believes that the comparative data presented, demonstrate that the CAD/CAMouflage Milling Blocks are 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 21 CFR 872.3690 that have previously been found to be substantially equivalent. The proposed, the predicate and reference devices consist of the same/similar Product Code: EBF, EBG, which are biocompatible for the same indications for use.

H. SUMMARY OF NON-CLINICAL TESTING

Non-clinical test data was used to support the substantial equivalency. Specifically, the CAD/CAMouflage Milling Blocks were evaluated using the relevant FDA recognized standard: **ISO 4049: 2009 Dentistry — Polymer-based restorative materials**. In addition, Prismatik utilized the **FDA's Guidance for Industry and FDA Staff - Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions**. To provide evidence and assurance for the device safety and meeting the **ISO 4049** and **ISO 10477:2004(E)** requirements, Prismatik performed various testing including the Flexural Strength, Water Sorption and Solubility, Radio Opacity, Shade Stability, Diametral Strength, Compressive Strength and biocompatibility.

I. CONCLUSION FROM THE NON-CLINICAL TESTING

The results of the above described studies demonstrate that the CAD/CAMouflage Milling Blocks are substantially equivalent to the cleared Primary Device: CERASMART™-K133824 and reference device: Prismatik's Camouflage Nanohybrid Composite-K133850.