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

October 1, 2015

Prismatik Dentalcraft, Inc.
Mr. Brandon Shepard
Regulatory Affairs & Quality Assurance Specialist
2212 Dupont Dr., Suite P
Irvine, California 92612

Re: K143515
Trade/Device Name: Inclusive® Zirconia Abutments compatible with: Zimmer Screw-Vent, Biomet 3i Certain and Nobel Biocare NobelReplace Implants
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 27, 2015
Received: August 28, 2015

Dear Mr. Shepard:

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,

for 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)*
k143515

Device Name
Inclusive® Zirconia Abutments compatible with: Zimmer Screw-Vent, Biomet 3i Certain and Nobel Biocare NobelReplace Implants.

Indications for Use *(Describe)*
Inclusive® Zirconia Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

Inclusive® Zirconia Abutments are compatible with the following bone-level implants:

- Biomet 3i™ Certain® internal hex implants with 3.4, 4.1, 5.0, 6.0 mm platform diameters
- Nobel Biocare NobelReplace® straight and tapered internal connection implants with NP, RP, WP, 6.0 mm platform diameters
- Zimmer Dental Screw-Vent® and Tapered Screw-Vent® internal hex implants with 3.5, 4.5, 5.7 mm platform diameters (excluding 3.3 mmD Screw-Vent implants)

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)*

PRISMATIK DENTALCRAFT, INC.

005

510(k) Summary

[As Required by 21 CFR 807.92]

A. SUBMITTER INFORMATION

Company Name:	PRISMATIK DENTALCRAFT, INC.
Company Address:	2212 Dupont Dr., Suite P Irvine, CA 92612
Company Phone / Fax:	(949) 225-1269 / (978) 313-0850
Primary Contact Person:	Marilyn Pourazar, (949) 225-1269 Senior Director, RA/QA
Date Summary Prepared:	September 30, 2015

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Inclusive® Zirconia Abutments compatible with: Zimmer Screw-Vent, Biomet 3i Certain and Nobel Biocare NobelReplace Implants.
Common Name:	Endosseous Dental Implant Abutment
Regulation Number:	872.3630
Product Code:	NHA
Device Class:	2
Review Panel:	Dental

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:

- Inclusive Zirconia Abutment Blanks (K083480)

D. DEVICE DESCRIPTION

Inclusive Zirconia Abutments are endosseous implant abutments which are placed into the dental implant to provide support for a prosthetic restoration. The

abutment is placed over the implant shoulder and is fastened into the implant with a screw.

The purpose of this 510(k) filing is to validate our inclusive abutment screw to be used with our Inclusive® Zirconia Abutments that are compatible with the following bone-level implants:

- Biomet 3i™ Certain® internal hex implants with 3.4, 4.1, 5.0, 6.0 mm platform diameters
- Nobel Biocare NobelReplace® straight and tapered internal connection implants with NP, RP, WP, 6.0 mm platform diameters
- Zimmer Dental Screw-Vent® and Tapered Screw-Vent® internal hex implants with 3.5, 4.5, 5.7 mm platform diameters (excluding 3.3 mmD Screw-Vent implants)

The predicate device utilizes an OEM abutment screw vs. the inclusive abutment screw used by the proposed device.

E. INDICATIONS FOR USE

Inclusive® Zirconia Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

Inclusive® Zirconia Abutments are compatible with the following bone-level implants:

- Biomet 3i™ Certain® internal hex implants with 3.4, 4.1, 5.0, 6.0 mm platform diameters
- Nobel Biocare NobelReplace® straight and tapered internal connection implants with NP, RP, WP, 6.0 mm platform diameters
- Zimmer Dental Screw-Vent® and Tapered Screw-Vent® internal hex implants with 3.5, 4.5, 5.7 mm platform diameters (excluding 3.3 mmD Screw-Vent implants)

F. NON-CLINICAL TESTING

Non-clinical test data was used to determine substantial equivalence with predicate devices.

Non-clinical testing was performed in accordance with FDA Guidance "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*" and it consisted of, Fatigue Testing and Static Load Failure Testing of finished assembled implant/abutment systems.

The testing performed demonstrated implant to abutment compatibility and has been used to support the substantial equivalence of the subject device to the identified predicate.

G. SUBSTANTIAL EQUIVALENCE

Inclusive®® Zirconia Abutments compatible with: Zimmer Screw-Vent, Biomet 3i Certain and Nobel Biocare NobelReplace Implants are substantially equivalent to the Inclusive Zirconia Abutment Blanks (K083480) identified in Section C above. They are substantially equivalent in intended use, materials, design and performance. To confirm the substantial equivalence, applicable performance tests such as Static Failure Load Testing and Fatigue Strength Testing have been performed, and the testing results and evaluations demonstrate the compatibility between the proposed and predicate devices. The detailed discussion and the testing procedure can be found in Section 018 (Performance Testing-Bench). The applicable standards that are used in this submission are listed below:

Applicable Standards	
ASTM F136-12a	Standard for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
AAMI/ANSI/ISO 10993-1:2009	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process (Biocompatibility)
ISO14801:2007	Dentistry - Implants - Dynamic fatigue test for endosseous dental implants
AAMI/ANSI 17665:-1:2006	Sterilization of health care products - Moist Heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
AAMI/ANSI/ISO 17665-2:2009	Sterilization of Health Care Products - Radiation - Part 2: Guidance of on the application of ISO 17665-1
ANSI/AAMI ST79:2010 &A1:2010 & A2:2011 & A3:2012 & A4:2013	(Consolidated Text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities

(See Comparison Tables below).

PRISMATIK DENTALCRAFT, INC.

Comparison of Predicate and Proposed Devices*:* Zimmer Screw-Vent Platform

Attributes	Predicate Device	Proposed Device	
	Inclusive Zirconia Abutment Blanks (K083480)	**Inclusive Zirconia Abutments compatible with: Zimmer Screw-Vent Platform**	**Similarities and Differences**
Manufacturer	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Dimensions of Abutment	Hex Dimensions: 2.4mm Across Flats 3.0mm Across Flats	Hex Dimensions: 2.4mm Across Flats 3.0mm Across Flats	Same
Abutment Screw Manufacturer	Zimmer (OEM)	Prismatik Dentalcraft, Inc.	The proposed device includes the inclusive abutment screw
Dimensions of Abutment Screw	Length 9mm; 1-72 UNF-2A Thread	Length 9mm; 1-72 UNF-2A Thread	Same
Indications for Use	The Inclusive Zirconia Abutment Blank is intended to be used in conjunction with endosseous implant in the maxillary and/or mandibular arch to provide support for crowns, bridges or overdenture prostheses. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	Inclusive Zirconia Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.	Same Intended Use.
Platform Compatibility	Zimmer Dental Screw-Vent 3.5, 4.5, 5.7mm	Zimmer Dental Screw-Vent 3.5, 4.5, 5.7mm (not compatible with 3.3mmD implant)	Same
Connection	Internal Hex	Internal Hex	Same
Design/Construction	Machined	Machined	Same
Anatomical Site	Oral Cavity	Oral Cavity	Same
Abutment Angle	0º-20º	0°-20º	Same
Implant Seat	Sits on a taper	Sits on a taper	Same
Screw Seat	Sits on a flat	Sits on a flat	Same
Material	Zirconia	Zirconia	Same

PRISMATIK DENTALCRAFT, INC.

Comparison of Predicate and Proposed Devices: Biomet 3i Certain Platform

Attributes	Predicate Device	Proposed Device	
	Inclusive Zirconia Abutment Blanks (K083480)	**Inclusive Zirconia Abutments compatible with: Biomet 3i Certain Implant System**	**Similarities and Differences**
Manufacturer	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Dimensions of Abutment	Hex Dimensions: 2.2mm Across Flats 2.7mm Across Flats	Hex Dimensions: 2.2mm Across Flats 2.7mm Across Flats	Same
Abutment Screw Manufacturer	Biomet 3i (OEM)	Prismatik Dentalcraft, Inc.	The proposed device includes the inclusive abutment screw
Dimensions of Abutment Screw	Length 10mm; M1.6 Thread	Length 10mm; M1.6 Thread	Same
Indications for Use	The Inclusive Zirconia Abutment Blank is intended to be used in conjunction with endosseous implant in the maxillary and/or mandibular arch to provide support for crowns, bridges or overdenture prostheses. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	Inclusive Zirconia Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.	Same Intended Use.
Platform Compatibility	Biomet 3i Certain 3.4, 4.1, 5.0, 6.0mm	Biomet 3i Certain 3.4, 4.1, 5.0, 6.0mm	Same
Connection	Internal Hex	Internal Hex	Same
Design/Construction	Machined	Machined	Same
Anatomical Site	Oral Cavity	Oral Cavity	Same
Abutment Angle	0º-20º	0º-20º	Same
Implant Seat	Sits on a flat	Sits on a flat	Same
Screw Seat	Sits on a flat	Sits on a flat	Same
Material	Zirconia	Zirconia	Same

PRISMATIK DENTALCRAFT, INC.

Comparison of Predicate and Proposed Devices*:* Nobel Biocare NobelReplace Platform

Attributes	Predicate Device	Proposed Device	
	Inclusive Zirconia Abutment Blanks (K083480)	**Inclusive Zirconia Abutments compatible with: Nobel Biocare NobelReplace Implant System**	**Similarities and Differences**
Manufacturer	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Same
Dimensions of Abutment	Cylindrical Diameter: 9.4mm Connection Length: .8mm	Cylindrical Diameter: 9.4mm Connection Length: .8mm	Same
Abutment Screw Manufacturer	Nobel Biocare (OEM)	Prismatik Dentalcraft, Inc.	The proposed device includes the inclusive abutment screw
Dimensions of Abutment Screw	Length 8.3mm; M1.8 Thread	Length 8.3mm; M1.8 Thread	Same
Indications for Use	The Inclusive Zirconia Abutment Blank is intended to be used in conjunction with endosseous implant in the maxillary and/or mandibular arch to provide support for crowns, bridges or overdenture prostheses. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	Inclusive Zirconia Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.	Same Intended Use.
Platform Compatibility	Nobel Biocare NobelReplace NP, RP, WP, 6.0	Nobel Biocare NobelReplace NP, RP, WP, 6.0	Same
Connection	Internal Trilobe	Internal Trilobe	Same
Design/Construction	Machined	Machined	Same
Anatomical Site	Oral Cavity	Oral Cavity	Same
Abutment Angle	0º-20º	0°-20º	Same
Implant Seat	Sits on a flat	Sits on a flat	Same
Screw Seat	Sits on a flat	Sits on a flat	Same
Material	Zirconia	Zirconia	Same