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

November 25,2014

Prismatik Dentalcraft, Incorporated
Mr. Brandon Shepard
Regulatory Affairs & Quality Assurance Specialist
2212 Dupont Drive, Suite P
Irvine, CA 92612

Re: K142118
Trade/Device Name: Inclusive® Titanium Abutments compatible with: Straumann Bone Level, Nobel Biocare Branemark , and Nobel Biocare NobelActive Implants.
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 24, 2014
Received: October 28, 2014

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,

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

Enclosure

PRISMATIK DENTALCRAFT, INC.

004 Indications for Use Statement

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)*
K142118

Device Name
Inclusive® Titanium Abutments compatible with: Straumann Bone Level, Nobel Biocare Branemark, and Nobel Biocare NobelActive Implants.

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

Inclusive® Titanium Abutments are compatible with:
- Straumann: Bone Level NC and RC implant sizes
- Nobel Biocare: Branemark RP size implant
- Nobel Biocare NobelActive NP and RP internal connection 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)*

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

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Food and Drug Administration
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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."

CONFIDENTIAL

005 510(k) Summary

[As Required by 21 CFR 807.92]

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements 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
Contact Person:	Primary Contact: Brandon Shepard, (949) 225-1243 Secondary Contact: Marilyn Pourazar, (949) 225-1269
Date Summary Prepared:	November 24, 2014

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Inclusive® Titanium Abutments compatible with: Straumann Bone Level, Nobel Biocare Branemark , and Nobel Biocare NobelActive 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 Titanium Abutment Blanks (K083192)

D. DEVICE DESCRIPTION

Inclusive Titanium 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. Abutments are made of titanium grade 23 (Ti-6AL-4V ELI) and meet ASTM F-136 Standard.

E. INDICATIONS FOR USE

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

Inclusive® Titanium Abutments are compatible with:
- Straumann: Bone Level NC and RC implant sizes
- Nobel Biocare: Branemark RP size implant
- Nobel Biocare NobelActive NP and RP internal connection implants

F. NON-CLINICAL TESTING

Non-clinical test data was used to evaluate the device's safety and effectiveness, and 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 Reliability Calculation, Fatigue Testing and Static Load Failure Testing of finished assembled implant/abutment systems.

In addition, sterilization validation information and a recommended sterilization method based on ANSI/AAMI ST79 and ISO 17665-1 is provided in the Information for Use.

The testing performed demonstrated implant to abutment compatibility and established that the predicate device is as safe, as effective, and performs as well or better than the predicate device(s).

G. SUBSTANTIAL EQUIVALENCE

Inclusive® Titanium Abutments compatible with Straumann Bone Level, Nobel Biocare Branemark, and Nobel Biocare NobelActive Implants are substantially equivalent to the Inclusive Titanium Abutment Blanks (K083192) identified in Section C above. They are substantially equivalent in intended use, materials, design and performance.

(See Comparison Tables below).

Comparison of Predicate and Proposed Devices*:* Straumann Bone Level Platform

	Predicate Device	Proposed Device	
	Inclusive Titanium Abutment Blanks (K083192)	**Inclusive Titanium Abutments compatible with: Straumann Bone Level Implants**	**Similarities and Differences**
Manufacturer	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	N/A
Dimensions of Abutment	Cylindrical Diameter: 9.4mm Connection Length: 2.735mm	Cylindrical Diameter: 9.4mm Connection Length: 2.735mm	Same
Abutment Screw Manufacturer	OEM (*Straumann*)	Inclusive (*Prismatik*)	Equivalent screw from different manufacturer
Dimensions of Abutment Screw	Length 7.85mm; M1.6 Thread	Length 7.85mm; M1.6 Thread	Same
Indications for Use	The Inclusive Abutment is intended to be used in conjunction with endosseous implants 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 Titanium 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. Different wording in the Indications for Use
Platform Compatibility	Straumann Bone Level NC and RC	Straumann Bone Level NC and RC	Same
Connection	Slot	Slot	Same
Design/Construction	Machined	Machined	Same
Anatomical Site	Oral Cavity	Oral Cavity	Same
Abutment Angle	0º-20º	0°-30º	Similar; increased angulation range
Implant Seat	Taper	Taper	Same
Screw Seat	Taper	Taper	Same
Material	Titanium Alloy	Titanium Alloy	Same

Comparison of Predicate and Proposed Devices: Nobel Biocare Branemark Platform

	Predicate Device	Proposed Device	
	Inclusive Titanium Abutment Blanks (K083192)	**Inclusive Titanium Abutments compatible with: Nobel Biocare Branemark Implants**	**Similarities and Differences**
Manufacturer	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	N/A
Dimensions of Abutment	Cylindrical Diameter: 9.4mm Across Flats Length: 2.71mm	Cylindrical Diameter: 9.4mm Across Flats Length: 2.71mm	Same
Abutment Screw Manufacturer	OEM (*Nobel Biocare*)	Inclusive (*Prismatik*)	Equivalent screw from different manufacturer
Dimensions of Abutment Screw	Length 7.3mm; M2.0 Thread	Length 7.3mm; M2.0 Thread	Same
Indications for Use	The Inclusive Abutment is intended to be used in conjunction with endosseous implants 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 Titanium 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. Different Indications for Use statement.
Platform Compatibility	Nobel Biocare Branemark RP	Nobel Biocare Branemark RP	Same
Connection	External Hex	External Hex	Same
Design/Construction	Machined	Machined	Same
Anatomical Site	Oral Cavity	Oral Cavity	Same
Abutment Angle	0º-20º	0°-30º	Similar; incrreased angulation range
Implant Seat	Flat	Flat	Same
Screw Seat	Flat	Flat	Same
Material	Titanium Alloy	Titanium Alloy	Same Titanium material

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

	Predicate Device	Proposed Device	
	Inclusive Titanium Abutment Blanks (K083192)	**Inclusive Titanium Abutments compatible with: Nobel Biocare NobelActive Implants**	**Similarities and Differences**
Manufacturer	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	N/A
Dimensions of Abutment	Cylindrical Diameter: 9.4mm Across Flats Length: 2.235mm	Cylindrical Diameter: 9.4mm Across Flats Length: 2.235mm	Same
Abutment Screw Manufacturer	OEM (*Nobel Biocare*)	Inclusive (*Prismatik*)	Equivalent screw from different manufacturer
Dimensions of Abutment Screw	Length 7.3mm; M1.6 Thread	Length 7.3mm; M1.6 Thread	Same
Indications for Use	The Inclusive Abutment is intended to be used in conjunction with endosseous implants 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 Titanium 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. Different Indications for Use statement.
Platform Compatibility	Nobel Biocare NobelActive NP, RP	Nobel Biocare NobelActive NP, RP	Same
Connection	Internal Hex	Internal Hex	Same
Design/Construction	Machined	Machined	Same
Anatomical Site	Oral Cavity	Oral Cavity	Same
Abutment Angle	0º-20º	0°-30º	Similar; increased angulation range
Implant Seat	Taper	Taper	Same
Screw Seat	Taper	Taper	Same
Material	Titanium Alloy	Titanium Alloy	Same