DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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November 16, 2015

PRISMATIK DENTALCRAFT, INC.
Mr. Armin Zehtabchi
Senior RA
2212 Dupont Drive, Suite P
Irvine, California 92612

Re: K151798
Trade/Device Name: Inclusive® Titanium Abutments compatible with: Straumann synOcta Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 14, 2015
Received: October 16, 2015

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 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,

Tina Kiang -S

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)*
K151798

Device Name
Inclusive® Titanium Abutments compatible with: Straumann synOcta Implant System

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

They are compatible with Straumann Standard Plus Tissue Level Implants in RN (4.1mm and 4.8 mm) and WN (4.8 mm) sizes.

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.

006_510 (K)-K151798 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 16, 2015

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Inclusive® Titanium Abutments compatible with: Straumann synOcta Implant System
21 CFR Reference:	21 CFR 872.3630
21 CFR Common Name:	Abutment, implant, dental, endosseous
Classification:	Class II, NHA
Panel:	Dental

PRISMATIK DENTALCRAFT, INC.

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:	Primary Predicate Device: Inclusive® Titanium Abutments compatible with: Straumann Tissue Level Implants, (K141211) Reference Device 1: Inclusive Titanium Abutments for NobelActive, Straumann Bone Level, Branemark, (K142118) Reference Device 2: ITI synOcta Meso Abutments**, (**K033243)

D. PROPOSED 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 mounted into the implant with a screw. Abutments and screws are made of titanium alloy (Ti-6AL-4V ELI) and meet ASTM F136 Standard. They are compatible with Straumann Standard Plus Tissue Level Implants in RN (4.1 mm and 4.8 mm) and WN (4.8 mm) sizes.

Prismatik Dentalcraft, Inc. provides premanufactured titanium abutments of a stock type with no inherent angulation which require further modification to obtain the desired shape before being used. The modifications are intended to be performed by dental laboratories with laboratory hand tools, as delineated in the device's instructions for use.

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.

They are compatible with Straumann Standard Plus Tissue Level Implants in RN (implant diameter: 4.1 mm and 4.8 mm) and WN (implant diameter: 4.8 mm) sizes.

F. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The comparison table below outlines and provides the similarities and the substantial equivalency of the Primary Predicate Device, the Inclusive® Titanium Abutments for Straumann Tissue Level Implants, K141211 (cleared by FDA on 10/22/2014), the Reference Device 1, the Inclusive Titanium Abutments for NobelActive, Straumann Bone Level, Branemark, (K142118), the Reference Device 2, the ITI synOcta Meso Abutments**, (**K033243) and the proposed device, the Inclusive® Titanium Abutments compatible with: Straumann synOcta Implant

System. The platform diameters and connection are the same for the Proposed Device and the Reference Device 2 (K033243). The connection for the Proposed Device and the Primary Predicate Device (K141211) is also the same.

Prismatik believes that the comparative data presented in the preceding paragraphs demonstrate that proposed device, Inclusive® Titanium Abutments compatible with: Straumann synOcta Implant System is substantially equivalent to 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 abutment, implant, dental, endosseous (21 CFR 872.3630) that have previously been found to be substantially equivalent. Any differences between the proposed device, the Inclusive® Titanium Abutments compatible with: Straumann synOcta Implant System, and the predicate device do not introduce any new issues of safety or effectiveness.

(See Comparison Table below)

PRISMATIK DENTALCRAFT, INC.

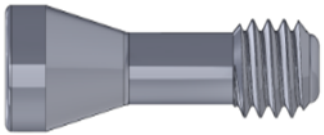
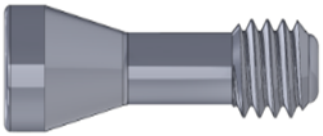
Table 1 – Comparison between Predicate and Proposed Device

Attributes	Primary Predicate Device	Reference Device (1)	Reference Device (2)	Proposed Device	Similarities / Differences
	Inclusive Titanium Abutments compatible with: Straumann Tissue Level Implants (K141211)	**Inclusive Titanium Abutments compatible with: Straumann Bone Level Implants (K142118)**	**ITI synOcta Meso Abutments (K033243)**	**Inclusive® Titanium Abutments compatible with: Straumann Tissue Level synOcta Implant System**	
	(Prismatik Dentalcraft, Inc.)	**(Prismatik Dentalcraft, Inc.)**	**Straumann USA**	**(Prismatik Dentalcraft, Inc.)**	
Indications for Use	Inclusive Titanium Abutments are pre-manufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid to prosthetic rehabilitation. Inclusive Titanium Abutments are compatible with Straumann Standard Plus Tissue Level Implants in RN (4.1 mm and 4.8 mm) and WN (4.8 mm) sizes.	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	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The ITI synOcta Meso abutments are indicated for cemented restorations in esthetic areas of the mouth. The abutment can be used in single tooth replacements and multiple tooth restorations.	Inclusive Titanium Abutments are pre-manufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid to prosthetic rehabilitation. They are compatible with Straumann Standard Plus Tissue Level Implants in RN (implant diameter: 4.1 mm and 4.8 mm) and WN (implant diameter: 4.8 mm) sizes.	Same as primary predicate

PRISMATIK DENTALCRAFT, INC.

Attributes	Primary Predicate Device	Reference Device (1)	Reference Device (2)	Proposed Device	Similarities / Differences
	Inclusive Titanium Abutments compatible with: Straumann Tissue Level Implants (K141211)	**Inclusive Titanium Abutments compatible with: Straumann Bone Level Implants (K142118)**	**ITI synOcta Meso Abutments (K033243)**	**Inclusive® Titanium Abutments compatible with: Straumann Tissue Level synOcta Implant System**	
Dimensions	Cylindrical Diameter: 9.4mm RN: diameter 4.8mm;	Cylindrical Diameter: 9.4mm Connection Length: 2.735mm	synOcta RN 4.8 mm	Cylindrical Diameter: 9.4mm RN: diameter 4.8mm;	Same as Primary Predicate Device and Reference Device # 2
	WN: diameter 6.5mm		synOcta WN 6.5 mm	WN: diameter 6.5mm	
Connection	Octagonal	Slot	Octagonal	Octagonal	Same as Primary Predicate Device and Reference Device # 2
Sterility	Packaged Non-sterile	Packaged Non-sterile	Packaged Non-sterile	Packaged Non-sterile	Same
Material	Titanium Alloy, Grade 23	Titanium Alloy, Grade 24	Ti-6AL-7Nb	Titanium Alloy, Grade 23	Same
Picture of Abutment					–

PRISMATIK DENTALCRAFT, INC.

Attributes	Primary Predicate Device	Reference Device (1)	Reference Device (2)	Proposed Device	Similarities / Differences
	Inclusive Titanium Abutments compatible with: Straumann Tissue Level Implants (K141211)	**Inclusive Titanium Abutments compatible with: Straumann Bone Level Implants (K142118)**	**ITI synOcta Meso Abutments (K033243)**	**Inclusive® Titanium Abutments compatible with: Straumann Tissue Level synOcta Implant System**	
Picture of Screw					–
Abutment Angle	None	0º-30º	-	0º-30º	Same as the Reference Device 1
Abutment Seat	Sits on a taper	Sits on a taper	Sits on a taper	Sits on a taper	Same
Screw Seat	Sits on a taper	Sits on a taper	Sits on a taper	Sits on a taper	Same
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity	Same
Construction	Machined	Machined	Machined	Machined	Same

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

Non-clinical test data was used to evaluate the proposed device's substantial equivalence compared to the predicate device.

Clinical testing was not necessary to establish substantial equivalency of the device.

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 testing finished assembled implant/abutment systems of the worst case scenario, through Reliability Calculation and Testing, as well as Fatigue Strength Testing and Static Load Failure Testing.

The testing performed demonstrated implant to abutment compatibility and has established substantial equivalency of the proposed device with predicate devices.

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

The proposed device, the Inclusive® Titanium Abutments compatible with: Straumann synOcta Implant System has the same performance specifications, fundamental scientific technology and intended use as that of the Prismatik's Primary Predicate device, the Inclusive® Titanium Abutments compatible with: Straumann Tissue Level Implants, K141211 (cleared by FDA on 10/22/2014), the Reference Device 1, the Inclusive Titanium Abutments for NobelActive, Straumann Bone Level, Branemark, K142118 (cleared by FDA on 11/25/2014) and the Reference Device 2, the ITI synOcta Meso Abutments**, (**K033243). These devices are substantially equivalent, and that any differences between the proposed device, the Inclusive® Titanium Abutments compatible with: Straumann synOcta Implant System and the cited primary predicate and reference devices do not introduce any new issues or concerns.