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 23, 2016

Prismatik Dentalcraft, Inc.
Ms. Maria E. Wagner
Sr. Specialist, Regulatory Affairs
2212 Dupont Drive, Suite P
Irvine, California 92612

Re: K153099
Trade/Device Name: Inclusive® Tapered Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 4, 2016
Received: May 5, 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,

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)*
K153099

Device Name
Inclusive® Tapered Implant System

Indications for Use *(Describe)*
Inclusive Tapered Implant System is indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

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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PRISMATIK DENTALCRAFT, INC.

007_510 (K) Summary-807.92

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:	2031503
Primary Contact Person:	Maria Wagner, (949) 440-2636 Senior Specialist, Regulatory Affairs Maria.wagner@glidewelldental.com
Secondary Contact Person	Shelly Harris, (949) 440-2629 Director of Regulatory Affairs & Quality Assurance Shelly.harris@glidewelldental.com
Date Summary Prepared:	May 18, 2016

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Inclusive® Tapered Implant System
21 CFR Reference:	21 CFR 872.3640
21 CFR Common Name:	Endosseous dental implant
Classification:	Class II, DZE, NHA
Panel:	Dental

C. IDENTIFICATION OF PREDICATE DEVICE

Primary Predicate:	Inclusive Tapered Implant System (K121406, Cleared on 2/22/2013)
Reference Predicate:	Hahn Tapered Implant System (K143353, Cleared on 4/2/2015)

D. PROPOSED DEVICE DESCRIPTION

The proposed device, Inclusive® Tapered Implant System, is manufactured from biocompatible Titanium alloy. The implant is designed with an internal hex connection with a diameter of implant with a 6-point flower (drawings are provided in the table below). Equipped with a tapered body and used to replace one or more missing teeth. The surface is blasted with Hydroxyl Apatite and acid etched. The dental implant (proposed device) will be provided sterile using gamma sterilization. The Inclusive Tapered Implant System, includes abutments in the form of healing abutments, engaging and non-engaging temporary abutments, straight and angled titanium abutments, titanium abutment fixation screws and straight multi-unit abutments.

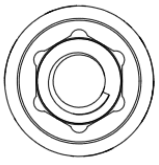
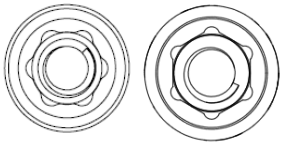
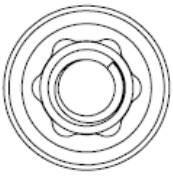
E. INDICATIONS FOR USE

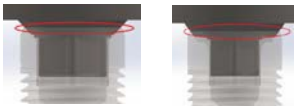
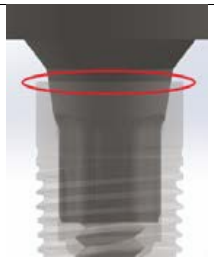
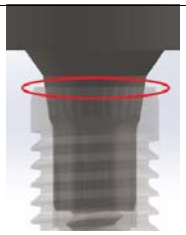
Inclusive® Tapered Implant System is indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

F. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The comparison table below outlines and provides the similarities and the substantial equivalency of the proposed device, the Inclusive® Tapered Implant System, to the predicate device, Inclusive® Tapered Implant System, K121406. Prismatik believes that the comparative data presented in the preceding paragraphs demonstrate that the proposed device is essentially the same as currently marketed devices for the same indications for use, same materials same fundamental scientific technology and design and supports our claim of substantial equivalence to predicate Class II devices under the classification of endosseous dental implant (21 CFR 872.3640) that have previously been found to be substantially equivalent. Any differences between the proposed device and the predicate device does not introduce new concerns in safety and efficacy.

Table 1 – Comparison between Predicate and Proposed Device

Attributes	Predicate Device	Referenced Device	Proposed Device	
	Inclusive Tapered Implant System (K121406)	**Hahn Tapered Implant System (K143353)**	**Inclusive Tapered Implant - 3.2 implant**	**Similarities and Differences**
Picture of Implant				Same as Predicate
Indications for Use	Inclusive Tapered Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.	Hahn Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.	Inclusive Tapered Implant System is indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.	Same
Surface	Blasted with Hydroxyl Apatite and acid etched	Blasted with Hydroxyl Apatite and acid etched	Blasted with Hydroxyl Apatite and acid etched	Same
Connection	 3.7 - 5.2: Internal Hex	 3.0: 6-point flower 3.5-7.0: Internal Hex	 3.2: 6-point flower	Same as reference
Design	Threaded root-form implant	Threaded root-form implant	Threaded root-form implant	Same
Implant Body Geometry	Screw Type	Screw Type	Screw Type	Same
Diameters (mm)	3.7, 4.7, 5.2	3.0, 3.5, 4.3, 5.0, 7.0	3.2	New: Additional Size
Lengths (mm)	**3.7 - 5.2**: 8, 10, 11.5, 13 & 16	**3.0**: 11.5, 13 & 16 **3.5 - 5.0**: 8, 10, 11.5, 13 & 16 **7.0**: 8, 10 & 11.5	**3.2**: 11.5, 13, and 16	Same

Attributes	Predicate Device	Referenced Device	Proposed Device	
	Inclusive Tapered Implant System (K121406)	**Hahn Tapered Implant System (K143353)**	**Inclusive Tapered Implant - 3.2 implant**	**Similarities and Differences**
Sterility	Packaged Sterile	Packaged Sterile	Packaged Sterile	Same
Material	Titanium Alloy, Grade 23	Titanium Alloy, Grade 23	Titanium Alloy, Grade 23	Same
Description of Abutment	Titanium abutments are made from titanium alloy. Titanium Abutments are prefabricated prosthetic components directly connected to endosseous dental implants and are intended to use as an aid to prosthetic rehabilitation.	Titanium abutments are made from, titanium alloy. Titanium Abutments are prefabricated prosthetic components directly connected to endosseous dental implants and are intended to use as an aid to prosthetic rehabilitation.	Titanium abutments are made from the same material, titanium alloy, Titanium Abutments are prefabricated prosthetic components directly connected to endosseous dental implants and are intended to use as an aid to prosthetic rehabilitation.	Same
Picture of Screw				Same as reference
Abutment Angle	0º-20º	0º-30º	0º-15º	within range of previous clearances
Description of Change	None	**None**	Addition of the 3.2 - External thread pattern of the Inclusive Implant combined with internal connection of the Hahn 3.0 (reference).	Additional size 3.2 mm
Abutment Seat	 3.7 - 5.2 sit on a taper	 Sits on a taper	 Sits on a taper	Same as reference

Attributes	Predicate Device	Referenced Device	Proposed Device	
	Inclusive Tapered Implant System (K121406)	**Hahn Tapered Implant System (K143353)**	**Inclusive Tapered Implant - 3.2 implant**	**Similarities and Differences**
Screw Seat	Sits on a flat	Sits on a taper	Sits on a Taper	Same as reference
Construction	Machined	Machined	Machined	Same

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

Non-clinical test data was used to support the substantial equivalency.
The functionality of the proposed Inclusive® Tapered Implant System, 3.2 as well as their conformance to design input was further determined by performance testing (Fatigue Testing and Static Load Failure Testing of finished assembled implant/abutment systems). The testing was performed in accordance with FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. The testing performed demonstrated implant to abutment compatibility. The applicable standards that are used in this submission are listed below:

Applicable Standards	
ISO 10993-1: 2009	Biological Evaluation of Medical Devices- Evaluation and testing
ISO 14971: 2012	Medical Devices —Application of risk management to medical devices
ASTM F136-13: 2013	Standard for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
ISO 14801:2007	Dentistry - Implants - Dynamic fatigue test for endosseous dental implants
BS EN 1641:2009	Dentistry — Medical devices for dentistry — Materials
ANSI-AAMI ST79: 2010 & A1: 2010 & A2: 2011 & A3: 2012	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
ISO 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

ISO 11137-1:2006+A: 2013	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2013	2013 Sterilization of health care products — Radiation Part 2: Establishing the sterilization

The proposed Inclusive® Tapered Implant System, 3.2 is manufactured from biocompatible titanium grade 23 (Ti-6AL-4V ELI) and meets ASTM F-136 Standard. In accordance with FDA Guidance "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*", in lieu of performing biocompatibility testing per ISO 10993-1 for the subject device, we have identified a Prismatik predicate device and a Prismatik reference device with identical materials, same manufacturing process, and same type/duration of patient contact:

- -**Primary Predicate**: K121406, Inclusive Tapered Implant System
- -**Reference Predicate**: K143353, Hahn Tapered Implant System

The proposed device, the Inclusive® Tapered Implant System, 3.2 consists of dental implants, abutments, and screws. The implant, healing abutments, and multi-unit abutments will be provided sterile. Abutments and fixation screws are provided non-sterile and sterilized prior to use. The sterilization and shelf life of all components of the device are supported by prior validation conducted for the applicant's own primary and reference predicate devices K121406 and K143353

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

The proposed device, the Inclusive® Tapered Implant System has the same performance specifications, fundamental scientific technology and intended use as that of the predicate device, Inclusive® Tapered Implant System, K121406 (Clearance letter dated February 22, 2013) and the reference device Hahn Tapered Implant System, K143353 (Clearance letter dated April 2, 2015). The performance data and a declaration of conformity with design controls supports a determination of continuing substantial equivalence of the proposed device to the predicate and referenced devices.