DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 7, 2015

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

Re: K151375
Trade/Device Name: Inclusive Titanium Abutments compatible with: Hiossen HG Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 21, 2015
Received: May 22, 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)*
TBD
K151375

Device Name
Inclusive® Titanium Abutments compatible with: Hiossen HG Implant System

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

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.

006_510 (K) 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:	September 25, 2015

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Inclusive® Titanium Abutments compatible with: Hiossen HG 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:	Predicate Device: Inclusive® Titanium Abutments for Astra Tech OsseoSpeed Implants–510(k)-K100993 Reference Device: HS/HG Prosthetic System–510(k)-k100245

D. PROPOSED DEVICE DESCRIPTION

Inclusive® Titanium Abutments for Hiossen HG Implant System are made of Titanium Alloy (Ti-6Al-4V) and are premanufactured prosthetic components connected directly to the endosseous dental implant and intended as an aid in prosthetic rehabilitation. They are compatible with Hiossen HG Implant System (Mini and Standard).

The anti-rotational feature for Inclusive® Titanium Abutment is a hexagon. The numerical value which defines the across flats of the hexagon is 2.10 mm for the Mini, and 2.50 mm for Standard. Both have a tolerance range of ±0.05 mm.

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 to prosthetic rehabilitation.

F. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Inclusive® Titanium Abutments compatible with: Hiossen HG Implant System is substantially equivalent to the Predicate Device, Inclusive® Titanium Abutments for Astra Tech OsseoSpeed Implants–510(k)-K100993, and the Reference Device, HS/HG Prosthetic System–510(k)-K100245 identified in Section C above. They are substantially equivalent in intended use, materials, design and performance.

(See Comparison Tables below)

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Table 1 – Comparison between Predicate and Proposed Device

Attribute	Reference Device (1)	Predicate Device (1)	Proposed Device	Similarities and Differences of Devices
	HS/HG Prosthetic System (K100245) Osstem Implant Co. Ltd (Subsidiary of Hiossen Inc)	**Inclusive® Titanium Abutment for Astra Tech OsseoSpeed™ Implants (K100993) Prismatik Dentalcraft, Inc.**	**Inclusive Titanium Abutments compatible with: Hiossen HG Implant System Prismatik Dentalcraft, Inc.**	
Dimensions of Abutment	Mini - 2.1 Across Flats of Hex Standard - 2.5 Across Flats of Hex	3.5/4.0 - 2.1 Across Flats of Hex 4.5/5.0 - 2.5 Across Flats of Hex	Mini - 2.1 Across Flats of Hex Standard - 2.5 Across Flats of Hex	Same
Dimensions of Abutment Screw	Mini - Length - 10.7mm, Screw Head - 2.2mm Standard - Length - 8.85mm, Screw Head - 2.5mm	3.5/4.0 - Length 8.25mm, Screw Head 2.33mm 4.5/5.0 - Length - 10.3mm, Screw Head 2.33mm	Mini - Length - 10.3mm, Screw Head - 2.2mm Standard - Length - 8.35mm, Screw Head - 2.3mm	Different screws dimensions
Indications for Use	HS/HG Prosthetic System is intended for use with the dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The Inclusive Titanium Abutments for Astra OsseoSpeed™ Implants are premanufactured prosthetic components directly connected to endlosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Astra Tech OsseoSpeed™ 3.0, 3.5, 4.0, 4.5, 5.0 implants.	Inclusive Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implant and are intended for use as an aid in prosthetic rehabilitation.	Similar intended use for the additional use with Hiossen mini 2.1 and Standard 2.5
Platform Diameter Compatibility	Hiossen HG Mini (2.1 Across Flats of Hex and Standard (2.5 Across Flats of Hex	Astra Tech OsseoSpeed™ Implants 3.5/4.0 4.5/5.0	Hiossen HG Mini - 2.1 Across Flats of Hex Standard - 2.5 Across Flats of Hex	Same as Reference predicate
Connection	Hexagonal	Hexagonal	Hexagonal	Same
Material	Titanium alloy (Ti-6AL-4V)	Titanium alloy (Ti-6AL-4V)	Titanium alloy (Ti-6AL-4V)	Same
Design / Construction	Machined	Machined	Machined	Same

Attribute	Reference Device (1)	Predicate Device (1)	Proposed Device	Similarities and Differences of Devices
	HS/HG Prosthetic System (K100245) Osstem Implant Co. Ltd (Subsidiary of Hiossen Inc)	**Inclusive® Titanium Abutment for Astra Tech OsseoSpeed™ Implants (K100993) Prismatik Dentalcraft, Inc.**	**Inclusive Titanium Abutments compatible with: Hiossen HG Implant System Prismatik Dentalcraft, Inc.**	
Anatomical Site / Placement	Oral Cavity / Tissue Level	Oral Cavity / Tissue Level	Oral Cavity / Tissue Level	Same
Abutment Angle	0-30°	0-20°	0-30°	Similar

G. NON-CLINICAL TESTING (PERFORMANCE DATA)

Non-clinical test data was used to evaluate the device's equivalence, 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, and the testing results and evaluations demonstrate the implant to abutment compatibility between the proposed and predicate/reference 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

Inclusive® Titanium Abutments are manufactured from biocompatible titanium grade 23 (Ti-6AL-4V ELI) and it 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 several of Prismatik own predicate devices with identical materials, same manufacturing process, and same type/duration of patient contact:

- K073217, Inclusive® Abutment for Zimmer, 3i and Nobel Biocare Implants
- K100993, Inclusive® Titanium Abutments for Astra OsseoSpeed Implants
- K121391, Inclusive® Titanium Abutment for Camlog Screw-Line Implants

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.

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

The proposed device, the Inclusive® Titanium Abutments compatible with: Hiossen HG Implant System have the same performance specifications, fundamental scientific technology and intended use as that of the Predicate Device, Inclusive® Titanium Abutments for Astra Tech OsseoSpeed Implants– 510(k)-K100993, and the Reference Device, HS/HG Prosthetic System–510(k)-K100245 identified in Section C above. The testing performed demonstrated implant to abutment compatibility and supports the substantial equivalence of the subject device to the identified predicate.