DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 6, 2017

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

Re: K170044
Trade/Device Name: Inclusive® Titanium Abutments compatible with: MegaGen AnyRidge® Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 8, 2017
Received: May 10, 2017

Dear Maria 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,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting 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)*
K170044

Device Name
Inclusive® Titanium Abutments compatible with: MegaGen AnyRidge® Implant System

Indications for Use *(Describe)*
Inclusive® Titanium Abutments are premanufactured prosthetic components connected to endosseous dental implants in the edentulous or partially edentulous maxilla or mandible to provide support for cement-retained or screw-retained prosthetic restorations.

All digitally designed abutments for use with Inclusive Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture.

Compatible Implant System: MegaGen AnyRidge® Implant System
Implant Diameter (mm) 3.5, 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
Platform Diameter (mm) 3.5 and 5.0

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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007_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:	949-440-2636
Company FAX:	(978) 313-0850
Facility Registration Number:	2031503
Primary Contact Person:	Maria E. Wagner, (949) 440-2636 Senior Specialist, Regulatory Affairs
Secondary Contact Person	Shelly Harris, (949) 440-2631 Director, RA/QA
Date Summary Prepared:	June 05, 2017

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Inclusive® Titanium Abutments compatible with: MegaGen AnyRidge Implant System
21 CFR Reference:	21 CFR 872.3630
21 CFR Common Name:	Endosseous dental Implant Abutment
Classification:	Class II, NHA
Panel:	Dental

C. IDENTIFICATION OF PREDICATE DEVICE

Primary Predicate:	Inclusive Abutments (K160979)
Reference Device:	Inclusive® Titanium Abutments for Astra OsseoSpeed Implants (K100993) XPEED AnyRidge Internal Implant System (K140091) Hahn Tapered Implant System (K143353) Inclusive Tapered Implant System (K121406) Shofu MonoCem Resin Cement (K020481)

D. PROPOSED DEVICE DESCRIPTION

Inclusive® Titanium Abutments compatible with: MegaGen AnyRidge Implant System are made of titanium alloy and have a prefabricated, precision interface (implant/ abutment connection) and are to be used for fabrication of patient-specific custom abutments using CAD/CAM technology. Each patient-specific abutment is individually prescribed by the clinician and manufactured by a Prismatik Dentalcraft authorized milling center. The proposed device is compatible with the MegaGen AnyRidge Implant System (K140091); 3.5, 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4mm implant diameter. Abutments are made from alloyed titanium Ti-6Al-4V ELI which meets ASTM standard F-136.

The Titanium Abutment Blanks are used for fabrication of all-titanium patient-specific abutments. These abutments include Multi-unit, Esthetic, and Straight Abutments. The Straight Abutments come in both Engaging and Non-Engaging connections. The Straight abutments 4.5 mm and 6.0 mm are used for support of CAD/CAM fabricated crowns / bridges or CAD/CAM fabricated zirconia copings. A patient-specific finished device for the 4.5 mm and 6.0 mm straight abutments will consist of both the titanium base and zirconia coping and will contain no angle correction.

E. INDICATIONS FOR USE

Inclusive® Titanium Abutments are premanufactured prosthetic components connected to endosseous dental implants in the edentulous or partially edentulous maxilla or mandible to provide support for cement-retained or screw-retained prosthetic restorations.

All digitally designed abutments for use with Inclusive Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture.

Compatible Implant System: MegaGen AnyRidge® Implant System
Implant Diameter (mm) 3.5, 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
Platform Diameter (mm) 3.5, 5.0.

F. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Inclusive® Titanium Abutments compatible with: MegaGen AnyRidge Implant System are substantially equivalent to the Titanium Abutments used in the MegaGen AnyRidge Implant System identified in Section C above. This includes the Multi-unit, Esthetic, Engaging and Non-Engaging Abutments. They are substantially equivalent in intended use, materials, design and performance. Provided below is Table 1 which provides a comparison between the predicate, referenced and proposed devices. Table 3 also provide additional referenced device with our CAD/CAM submission.

Inclusive® Titanium (Multi-unit, Esthetic, Engaging and Non-Engaging), Abutments are fabricated to be compatible with the predicate device connection.

They are substantially equivalent in intended use, materials, design and performance with the reference predicates as depicted in Table 2 and 2A below (2A is specific to 4.5 mm and 6.0mm).

The differences between the predicate and proposed devices have been evaluated per the testing described in section G (*non-clinical testing*) and the proposed device is substantially equivalent to the predicate *(See Comparison Tables below).*

PRISMATIK DENTALCRAFT, INC.

Table 1 – Comparison between Predicate and Proposed Device

Attributes	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device	Proposed Device	Similarities and Differences
	Inclusive Abutments	Xpeed AnyRidge Implant System	Inclusive Titanium Abutments for AstraTech OsseoSpeed Implants	Hahn Tapered Implant System	Inclusive Tapered Implant System	Inclusive Titanium Abutments compatible with: MegaGen AnyRidge Implant System	N/A
510(k) number	K160979	K140091	K100993	K143353	K121406	K170044	N/A
Manufacturer:	Prismatik Dentalcraft Inc.	Megagen Implant Co., Ltd.	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	N/A
Indications for Use	Inclusive Abutments are premanufactured prosthetic components connected to endosseous dental implants in the edentulous or partially edentulous maxilla or mandible to provide support for cement-retained or screw-retained	The Xpeed AnyRidge® Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and	Inclusive Titanium Abutments for Astra OsseoSpeed Implants are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.	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	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	Inclusive® Titanium Abutments are premanufactured prosthetic components connected to endosseous dental implants in the edentulous or partially edentulous maxilla or mandible to provide support for cement-retained or	The indications for use is the same as our primary predicate. The only difference is the implant compatibility to the Ref. Device (K140091).

Attributes	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device	Proposed Device	Similarities and Differences
	Inclusive Abutments	Xpeed AnyRidge Implant System	Inclusive Titanium Abutments for AstraTech OsseoSpeed Implants	Hahn Tapered Implant System	Inclusive Tapered Implant System	Inclusive Titanium Abutments compatible with: MegaGen AnyRidge Implant System	N/A
510(k) number	K160979	K140091	K100993	K143353	K121406	K170044	N/A
	prosthetic restorations. All digitally designed abutments for use with Inclusive® Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture	overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar	They are compatible with the Astra Tech OsseoSpeed 3.0, 3.5, 4.0, 4.5, 5.0 implants.	and appropriate occlusal loading.	the presence of primary stability and appropriate occlusal loading.	screw-retained prosthetic restorations. All digitally designed abutments for use with Inclusive Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture. Compatible Implant System: MegaGen AnyRidge® Implant System	

Attributes	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device	Proposed Device	Similarities and Differences
	Inclusive Abutments	Xpeed AnyRidge Implant System	Inclusive Titanium Abutments for AstraTech OsseoSpeed Implants	Hahn Tapered Implant System	Inclusive Tapered Implant System	Inclusive Titanium Abutments compatible with: MegaGen AnyRidge Implant System	N/A
510(k) number	K160979	K140091	K100993	K143353	K121406	K170044	N/A
		region and are indicated for delayed loading.				Implant Diameter (mm) 3.5, 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4 Platform Diameter (mm) 3.5 and 5.0	
Platform Compatibility	3.0-7.0mm	Fixture Diameters: 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4mm	Implant diameters: 3.0, 3.5, 4.0, 4.5, 5.0mm	3.0, 3.5, 4.3, 5.0 and 7.0mm	3.7, 4.7, and 5.2mm	Implant Diameters: 3.5, 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4mm	Same as reference device
Connection	Hexagon	Hexagon	Hexagon	Hexagon	Hexagon	Hexagon	Same
Material	Ti-6Al-4V ELI	CP Ti Grade 4	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Same as predicate
Design/Construction	Machined	Machined	Machined	Machined	Machined	Machined	Same
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity	Same
Implant Seat	Sits on a Taper	Sits on a Taper	Sits on a Taper	Sits on a Taper	Sits on a Taper	Sits on a Taper	Same
Screw Seat	Sits on a Flat	Sits on a Flat	Sits on a Flat	Sits on a Flat	Sits on a Flat	Sits on a Flat	Same

Attributes	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device	Proposed Device	Similarities and Differences
	Inclusive Abutments	Xpeed AnyRidge Implant System	Inclusive Titanium Abutments for AstraTech OsseoSpeed Implants	Hahn Tapered Implant System	Inclusive Tapered Implant System	Inclusive Titanium Abutments compatible with: MegaGen AnyRidge Implant System	N/A
510(k) number	K160979	K140091	K100993	K143353	K121406	K170044	N/A
Conclusion:	The comparison above outline the similarities between the predicate and proposed devices. Prismatik has presented comparative data in the preceding paragraphs that demonstrate that Inclusive® Titanium Abutments are substantially equivalent to the predicate device. Any differences between the proposed device and the predicate device do not introduce any new concerns of safety and effectiveness.						

Table 2 Comparison of variation of Abutments (Multi-Unit, Esthetic, Engaging and Non-Engaging)

Attributes	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device	Proposed Device	Similarities and Differences
	Inclusive Abutments	Xpeed AnyRidge Implant System	Inclusive Titanium Abutments for AstraTech OsseoSpeed Implants	Hahn Tapered Implant System	Inclusive Tapered Implant System	Inclusive Titanium Abutments compatible with: MegaGen AnyRidge Implant System	
510(k) Number	K160979	K140091	K100993	K143353	K121406	K170044	N/A
Multi-Unit Abutments	Multi-Unit Abutments are provided in 0°, 17°, or 30° configurations	N/A	N/A	Multi-Unit Abutments are provided in 0°, 17°, or 30° configurations	N/A	Multi-Unit Abutments are provided in 0°, 17°, or 30° configurations	Same as Hahn Tapered Implant (reference K143353)
Esthetic Abutments	N/A	Angled Abutment	N/A	N/A	N/A	Angled Abutment	Same as Reference (K140091)
4.5mm Non-Engaging Abutments	4.5 mmH abutments have a 4 mm post height	N/A	N/A	N/A	N/A	4.5 mmH abutments have a 4 mm post height	Same as predicate (K160979)
4.5/6.0mm Engaging Abutments	4.5/6 mmH abutments have a 4 mm or 5.5 mm post heights	N/A	N/A	N/A	N/A	4.5/6 mmH abutments have a 4 mm or 5.5 mm post heights	Same as predicate (K160979)

The Multi-Unit, Esthetic, and Engaging abutment connection geometries are hexagon shaped and there is no connection geometry for the non-engaging. Please note the 4.5 and 6.0 mm are for straight abutments only.
The materials for all variations of abutments are the same, Ti-6Al-4V ELI.

Table 2A: Design Parameters (4.5 mm and 6.0 mm)
The subject device is substantially equivalent in indications and design principles to predicate devices shown above. Below is a summary table comparing the subject device, the primary predicate device and the additional reference predicate device.

	Subject Device	**Primary Predicate Device**
Comparison	Prismatik Dentalcraft, Inc. (K170044)	Inclusive Abutments (K160979)
Design		
Abutment Design	Titanium Blank for CAD/CAM Titanium Abutment for CAD/CAM	Titanium Blank for CAD/CAM Titanium Abutment for CAD/CAM
Prosthesis Attachment	Cement-retained Screw retained	Cement-retained Screw retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit
Abutment Platform Diameter	3.5 – 8.4mm	3.0-7.0mm
Abutment Angle	Straight only	Straight only
Material		
Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Coping	Y-TZP	Y-TZP
Screw	Ti-6Al-4V ELI	Ti-6Al-4V ELI

Please note the 4.5 and 6.0 mm are for straight abutments only.

G. NON-CLINICAL TESTING (PERFORMANCE DATA)

The technological characteristics of the subject device have been verified to be essentially the same as the predicate device based on assessments of material composition, dimensional features, and mechanical properties. 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*".

Summary of Testing:
The technological characteristics of the Inclusive Titanium Abutments compatible with MegaGen AnyRidge Implant System have been verified to be essentially the same as the predicate devices based on assessments of materials composition, dimensional features, mechanical properties and biocompatibility of the implant and instrument materials.

Comparative testing was performed to show equivalence to the predicate device. This testing was performed according to ISO 14801:2007. This consisted of Reliability Calculation, Fatigue Testing and Static Load Failure Testing of finished assembled implant/abutment systems.

Reverse engineering analysis of critical features was performed on OEM implant bodies, OEM abutments, and OEM abutment fixation screws to establish compatibility.

The proposed device is made of the same material (medical grade titanium) as indicated in our reference devices K121406 and K143353. All the applicable Biocompatibility testing (Sensitization, Irritation, Cytotoxicity, and Systemic Toxicity) has been conducted for these Devices. Hence, no additional biocompatibility testing was deemed necessary for this submission.

Sterile Product:
The Inclusive® Multi-Unit Abutments are provided sterilized via a minimum of 25KGy dose of gamma radiation to ensure SAL 10^{-6}. The sterilization dose was determined using the Method VD_{max25} Dose Audit in accordance with ANSI/AAMI/ISO 11137-2:2013 Sterilization of Health Care Products - Radiation - Part 2: Establishing the Sterilization Dose.

Non-Sterile Product
Inclusive® Titanium Abutments compatible with: MegaGen and abutment screws are single-use devices, and are being shipped non-sterile, as they require further modification. After modification, and prior to clinical use, dental abutments and screws must be cleaned, disinfected, and sterilized according to a validated method, as described in the IFU. The recommended sterilization validation method is based on ANSI/AAMI ST79 and ISO 17665-1 and is provided in the reference predicates K160979 and K143353.

No clinical test data was used to support the decision of substantial equivalence.

Conclusion:

In accordance with Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notifications the Inclusive Titanium Abutments compatible with: MegaGen AnyRidge Implant System is substantially equivalent to the predicate devices as described.