August 5, 2019

Prismatik Dentalcraft, Inc.
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K191222
Trade/Device Name: Inclusive® Titanium Abutments compatible with: Dentsply Implants Astra Tech Implant System® EV
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 6, 2019
Received: May 7, 2019

Dear Kevin Thomas:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*

K191222

Device Name

Inclusive® Titanium Abutments compatible with: Dentsply Implants Astra Tech Implant System® EV

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 Titanium Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture.

Compatible Implant System: Dentsply Implants Astra Tech Implant System® EV

Compatible Implant Fixtures	Implant Body Diameter	Implant Platform Diameter
OsseoSpeed® EV 3.0S	3.0 mm	3.0 mm
OsseoSpeed® EV 3.6S	3.6 mm	3.6 mm
OsseoSpeed® EV 4.2S	4.2 mm	4.2 mm
OsseoSpeed® EV 4.2C	3.6 mm	4.2 mm
OsseoSpeed® EV 4.8S	4.8 mm	4.8 mm
OsseoSpeed® EV 4.8C	4.2 mm	4.8 mm
OsseoSpeed® EV 5.4S	5.4 mm	5.4 mm

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.

510(k) Summary – K191222

Inclusive® Titanium Abutments compatible with: Dentsply Implants Astra Tech Implant System® EV

Prismatik Dentalcraft, Inc.

August 5, 2019

ADMINISTRATIVE INFORMATION

Manufacturer Name	Prismatik Dentalcraft, Inc. 2212 Dupont Drive, Suite P Irvine, CA 92612 Telephone: +1 949-440-2629 Fax: +1 978-313-0850
Official Contact	Herbert Schoenhoefer, Director of RA/QA So Hyun Park, Regulatory Affairs Specialist
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Inclusive® Titanium Abutments compatible with: Dentsply Implants Astra Tech Implant System® EV
Common Name	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate
K170044, Inclusive® Titanium Abutments compatible with: MegaGen AnyRidge® Implant System, Prismatik Dentalcraft, Inc.

Reference Devices
K120414, OsseoSpeed™ Plus, Astra Tech AB
K073217, Inclusive™ Abutment for Zimmer, 3i and Nobel Biocare Implants, Inclusive Dental Solutions
K083192, Inclusive Titanium Abutment Blanks, Inclusive Dental Solutions
K160979, Inclusive Abutments, Prismatik Dentalcraft, Inc.

INDICATIONS FOR USE STATEMENT

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 Titanium Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture.
Compatible Implant System: Dentsply Implants Astra Tech Implant System® EV

Compatible Implant Fixtures	Implant Body Diameter	Implant Platform Diameter
OsseoSpeed® EV 3.0S	3.0 mm	3.0 mm
OsseoSpeed® EV 3.6S	3.6 mm	3.6 mm
OsseoSpeed® EV 4.2S	4.2 mm	4.2 mm
OsseoSpeed® EV 4.2C	3.6 mm	4.2 mm
OsseoSpeed® EV 4.8S	4.8 mm	4.8 mm
OsseoSpeed® EV 4.8C	4.2 mm	4.8 mm
OsseoSpeed® EV 5.4S	5.4 mm	5.4 mm

SUBJECT DEVICE DESCRIPTION

Inclusive® Titanium Abutments compatible with: Dentsply Implants Astra Tech Implant System EV, which are the subject of this submission, are designed and fabricated to be compatible exclusively with Dentsply Implants Astra Tech Implant System EV, and have a prefabricated, precision interface (implant/abutment connection) compatible with the primary predicate device connection. The proposed product line includes stock abutments and abutments intended for fabrication of patient-specific custom abutments using CAD/CAM technology. Each patient-specific abutment is individually prescribed by the clinician and manufactured by an authorized milling center validated by Prismatik Dentalcraft.

The subject devices are manufactured from titanium alloy conforming to ASTM F136, and have a taper followed by a keyway connection feature that prevents rotation of the abutment. The abutments are compatible exclusively with the Astra Tech OsseoSpeed EV implant line (cleared under K120414) in the following diameters: 3.0S, 3.6S, 4.2S, 4.2C, 4.8S, 4.8C, 5.4S mm. The subject device includes the following components: Titanium Abutment Blanks, intended to be used to fabricate all-titanium, patient-specific abutments using CAD/CAM technology; Titanium Abutment 4.5mmH and Titanium Abutment 6mmH, intended to be used for support of CAD/CAM fabricated crowns/bridges or zirconia copings; Titanium Esthetic Abutments, prefabricated abutments intended to be connected directly to an endosseous implant for retention of a prosthesis in straight and 15° angled designs; and Titanium Screws, indicated for the temporary or long-term retention of the abutments to the compatible dental implant fixtures. All subject device components are provided non-sterile.

Titanium Abutment 4.5mmH and 6mmH are two-piece abutments. The crowns/bridges or zirconia copings produced at the validated milling center compose the second part of the two piece abutment.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: sterilization validation according to ISO 17665-1, and referenced from K073217, K083192, and K160979; biocompatibility

according to ISO 10993-5 and ISO 10993-12, and referenced from K160979; reverse engineering of OEM implant bodies, abutments, and abutment screws to confirm compatibility; and static compression and compression fatigue testing according to ISO 14801. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference device listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device K170044, and the reference device K120414.

The subject device is substantially equivalent to the primary predicate device K170044 in intended use, material, design, and performance. The subject device and the primary predicate device K170044 each include prefabricated, precision interface (implant/abutment connection) abutments that are manufactured from titanium alloy conforming to ASTM F136. The subject device and the primary predicate device K170044 each include stock abutments and abutments intended 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 an authorized milling center validated by Prismatik Dentalcraft.

The purpose of including the reference device K120414 is to support the indication for use of the subject device with the compatible Astra Tech OsseoSpeed® EV implants 3.0S, 3.6S, 4.2S, 4.2C, 4.8S, 4.8C, and 5.4S. The reference devices K073217, K083192, and K160979 are included to reference prior sterilization validation information; K160979 also is included to reference prior biocompatibility information.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate K170044. Slight differences in language of the subject device and primary predicate device Indications for Use statements do not affect the intended use as endosseous dental implant abutments for the support of a prosthesis to restore chewing function. Minor differences in language of the subject device and primary predicate device IFUS are related to the specific device names and the compatible OEM implant lines. None of these minor differences impact safety or effectiveness because both IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

Similarly, the differences between the subject device IFUS and that of the reference device are related to the specific device names and design features, and the compatible implant lines. None of these minor differences impact safety or effectiveness because all IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

The subject device designs are substantially equivalent to the corresponding designs of the primary predicate device K170044, including titanium blank abutments, titanium base abutments (engaging and non-engaging), and esthetic abutments. The subject device and the primary predicate device K170044 are for single-unit or multi-unit restorations, are for cement-retained or screw-retained prostheses, have internal implant interface connections, and are made of Ti-6Al-4V alloy (abutments and abutment screws), and the titanium base abutments are to be used with zirconia superstructures.

The subject device includes designs for implant platforms ranging from 3.0 mm to 5.4 mm. The primary predicate K170044 includes implant platform sizes of 3.5 mm to 5.0 mm. Substantial equivalence of the range of platform sizes of the subject device are supported by the reference device K120414.

The subject device includes designs for abutment angulation up to 20°; this angulation is within the range of abutment angulation of the primary predicate device K170044 and is the same range as the reference device K120414.

The difference in compatible OEM implant designs between the subject device and the primary predicate device K17044 are mitigated by dimensional analysis and reverse engineering analysis regarding specific critical dimensions. When the subject device is used according to its labeling, this difference does not impact safety or effectiveness.

The subject device is to be sterilized by the end-user, the same as the primary predicate device K170044. Sterilization validation for the subject device was performed according to ISO 17665-1. This validated sterilization method is the same as that for the primary predicate device K170044, and the reference devices K073217, K083192, and K160979.

Substantial equivalence of the subject device components in terms of biocompatibility is supported by the fact that materials are identical in formulation, processing, component interactions, and storage conditions to the predicate devices in K170044. The biocompatibility testing included in the previous 510(k) submissions, K160979 and K170044, were referenced as the confirmatory biocompatibility testing of the subject device.

Mechanical performance testing was performed according to ISO 14801. Worst-case constructs were subjected to static compression and compression fatigue testing. The fatigue limit data demonstrated that the subject device has sufficient strength for its intended use.

CONCLUSION

The subject device, the primary predicate device, and the reference device have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device, the primary predicate, and reference device encompass the same range of physical dimensions, are packaged in similar materials, and are to be sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Table of Substantial Equivalence

<table>
<tr><th rowspan="2">Comparison</th><th>Subject Device</th><th>Primary Predicate Device</th><th>Reference Device</th></tr>
<tr><td>Inclusive® Titanium Abutments compatible with:
Dentsply Implants Astra Tech Implant System® EV
Prismatik Dentalcraft, Inc.</td><td>K170044
Inclusive® Titanium Abutments compatible with:
MegaGen AnyRidge® Implant System
Prismatik Dentalcraft, Inc.</td><td>K120414
OsseoSpeed™ Plus

Astra Tech AB</td></tr>
<tr><td>Indications for Use Statement</td><td>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 Titanium Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture.
Compatible Implant System: Dentsply Implants Astra Tech Implant System® EV
<table><tr><th>Compatible Implant Fixtures</th><th>Implant Body Diameter</th><th>Implant Platform Diameter</th></tr><tr><td>OsseoSpeed® EV 3.0S</td><td>3.0 mm</td><td>3.0 mm</td></tr><tr><td>OsseoSpeed® EV 3.6S</td><td>3.6 mm</td><td>3.6 mm</td></tr><tr><td>OsseoSpeed® EV 4.2S</td><td>4.2 mm</td><td>4.2 mm</td></tr><tr><td>OsseoSpeed® EV 4.2C</td><td>3.6 mm</td><td>4.2 mm</td></tr><tr><td>OsseoSpeed® EV 4.8S</td><td>4.8 mm</td><td>4.8 mm</td></tr><tr><td>OsseoSpeed® EV 4.8C</td><td>4.2 mm</td><td>4.8 mm</td></tr><tr><td>OsseoSpeed® EV 5.4S</td><td>5.4 mm</td><td>5.4 mm</td></tr></table></td><td>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</td><td>[Implant portion of IFUS not applicable to subject device]
Abutments:
Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.
Atlantis Abutments:
The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous; patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.
The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous; implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous; patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.</td></tr>
<tr><td>Reason for Predicate / Reference Device</td><td>Not applicable</td><td>IFUS; Abutment designs</td><td>Compatible implant fixtures</td></tr>
<tr><td>Summary</td><td></td><td></td><td></td></tr>
<tr><td>Compatible Implant Diameters</td><td>3.0, 3.6, 4.2, 4.8, 5.4 mm</td><td>3.5, 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4 mm</td><td>3.0, 3.6, 4.2, 4.8, 5.4 mm</td></tr>
<tr><td>Compatible Astra Tech OsseoSpeed™ EV Implants</td><td>3.0S, 3.6S, 4.2S, 4.2C, 4.8S, 4.8C, 5.4S</td><td>Not applicable</td><td>3.0S, 3.6S, 4.2S, 4.2C, 4.8S, 4.8C, 5.4S</td></tr>
<tr><td>Abutment Platform Sizes</td><td>3.0 mm – 5.4 mm</td><td>3.5 mm – 5.0 mm</td><td>3.0 mm – 5.4 mm</td></tr>
<tr><td>Abutment Margin Height</td><td>0.5 mm – 6.0 mm</td><td>0.5 mm – 6.5 mm</td><td>1.0 mm – 7.0 mm</td></tr>
<tr><td>Abutment Angle</td><td>0º – 20º</td><td>0º – 30º</td><td>0º – 30º</td></tr>
<tr><td>Prosthesis Attachment</td><td>Cement-retained, Screw-retained</td><td>Cement-retained, Screw-retained</td><td>Cement-retained, Screw-retained</td></tr>
<tr><td>Restoration</td><td>Single-unit, Multi-unit</td><td>Single-unit, Multi-unit</td><td>Single-unit, Multi-unit</td></tr>
<tr><td>Abutment Designs</td><td></td><td></td><td></td></tr>
<tr><td>Titanium Abutment Blank</td><td>Provided in 9.4 mm diameter;
to machine a patient-specific, engaging, one-piece abutment</td><td>Provided in 9.4 mm diameter;
to machine a patient-specific one-piece abutment</td><td>Not applicable</td></tr>
<tr><td>Prosthetic Post Height</td><td>4.0 mm minimum</td><td>4.0 minimum</td><td></td></tr>
<tr><td>Margin Height</td><td>0.5 mm minimum; 6 mm maximum</td><td>0.5 mm minimum; 6 mm maximum</td><td></td></tr>
</table>

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate Device	Reference Device
	Inclusive® Titanium Abutments compatible with: Dentsply Implants Astra Tech Implant System® EV Prismatik Dentalcraft, Inc.	K170044 Inclusive® Titanium Abutments compatible with: MegaGen AnyRidge® Implant System Prismatik Dentalcraft, Inc.	K120414 OsseoSpeed™ Plus Astra Tech AB
Angulation	20° maximum	30° maximum	
Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	
Restoration Types	Single-unit, Multi-unit	Single-unit, Multi-unit	
Titanium Abutment Engaging	Engaging, two-piece abutment	Engaging, two-piece abutment	Designs: Cover screws, healing abutments, temporary abutments, cast-to abutments, ball abutments, straight abutments, angled abutments Angulation: Straight (0°), 15° to 30° Prosthesis attachment: Cement-retained, Screw-retained Restoration types: Single-unit, Multi-unit Additional details not provided in 510(k) Summary
Prosthetic Post Height	4 mm, 5.5 mm	4 mm, 5.5 mm	
Margin Height	0.5 mm minimum, 6 mm maximum	1 mm	
Angulation	0°	0°	
Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	
Restoration Types	Single-unit, Multi-unit	Single-unit, Multi-unit	
Titanium Abutment Non-Engaging	Non-engaging, two-piece abutment	Non-Engaging, two-piece abutment	
Prosthetic Post Height	4 mm minimum	4 mm	
Margin Height	0.5 mm minimum, 6 mm maximum	0.5 mm	
Angulation	0°	0°	
Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	
Restoration Types	Single-unit, Multi-unit	Single-unit, Multi-unit	
Titanium Esthetic Abutment	Engaging; one-piece; cemented prosthesis	Engaging; one-piece; cemented prosthesis	
Prosthetic Post Height	4 mm minimum, 6.5 mm maximum	6.5 mm	
Margin Height	1.5 mm, or 3 mm	1.5 mm, or 3 mm	
Angulation	0°; 15° for anterior region; 15° for posterior region	0°; 15° for anterior region; 15° for posterior region	
Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	
Restoration Types	Single-unit, Multi-unit	Single-unit, Multi-unit	
Materials			
Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Not stated in 510(k) Summary
Coping/Superstructure	Y-TZP	Y-TZP	Zirconia
Screw	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Not stated in 510(k) Summary