



Food and Drug Administration
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January 6, 2015

Prismatik Dentalcraft, Incorporated
Mr. Brandon Shepard
Regulatory Affairs & Quality Assurance Specialist
2212 Dupont Drive, Suite P
Irvine, CA 92612

Re: K141923
Trade/Device Name: Inclusive® Titanium Abutments, compatible with Dentsply
Implants Ankylos® C/X
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 5, 2014
Received: December 8, 2014

Dear Mr. Shepard,

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,

A handwritten signature in black ink that reads "Susan Runno DDS, MA". The signature is written in a cursive style. In the background, there is a faint, large watermark of the letters "FDA".

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

004 **Indications for Use Statement**

510(k) Number (if known): K141923

Device Name: Inclusive[®] Titanium Abutments, compatible with
Dentsply Implants Ankylos[®] C/X

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.

Inclusive Titanium Abutments are compatible with
Dentsply Implants Ankylos[®] C/X in 3.5, 4.5, 5.5, 7.0 mm sizes.

Type of Use

Prescription Use: Yes No
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use: Yes No
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

005

510(k) Summary

[As Required by 21 CFR 807.92]

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements 21 CFR 807.92.

A. SUBMITTER INFORMATION

Company Name: PRISMATIK DENTALCRAFT, INC.

Company Address: 2212 Dupont Dr., Suite P
Irvine, CA 92612

Company Phone / Fax: (949) 225-1269 / (978) 313-0850

Contact Person: Primary Contact:

- Brandon Shepard, RA/QA Specialist
(949) 225-1243

Secondary Contact:

- Marilyn Pourazar, Sr. Director RA/QA
(949) 225-1269

Date Summary Prepared: December 5, 2014

B. DEVICE IDENTIFICATION

Trade/Proprietary Name: Inclusive[®] Titanium Abutments,
compatible with Dentsply Implants Ankylos[®] C/X

Common Name: Endosseous Dental Implant Abutment

Regulation Number: 872.3630

Product Code: NHA

Device Class: 2

Review Panel: Dental

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name: Atlantis Abutment for Dentsply Ankylos Implant (K101004)
Inclusive Titanium Abutment Blanks (K083192)

D. 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 F-136 Standard. Inclusive Titanium Abutments are compatible with Dentsply Implants Ankylos C/X in 3.5 mm, 4.5 mm, 5.5 mm, and 7.0 mm Ø sizes. Physical and technological characteristics of the proposed device are summarized in the comparison table below.

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.

Inclusive Titanium Abutments are compatible with Dentsply Implants Ankylos C/X in 3.5, 4.5, 5.5, 7.0 mm sizes.

F. SUBSTANTIAL EQUIVALENCE

Inclusive Titanium Abutments, compatible with Dentsply Implants Ankylos C/X, are substantially equivalent to the Atlantis Abutment for Dentsply Ankylos Implant (K101004) and the Inclusive Titanium Abutment Blanks (K083192). They are substantially equivalent in intended use, materials, as well as design, technological characteristics and performance.

G. NON-CLINICAL TESTING

Non-clinical test data was used to evaluate the proposed device's safety and effectiveness, and determine substantial equivalence with predicate devices. 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.

In addition, sterilization validation information and recommended sterilization method based on ANSI/AAMI ST79 and ISO 17665-1 is provided in the Information for Use.

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

H. **CONCLUSION**

The results of the nonclinical testing performed, demonstrate that Inclusive Titanium Abutments, compatible with Dentsply Implants Ankylos C/X are as safe, as effective, and perform as well as the predicate devices. Therefore the proposed device is substantially equivalent with the predicate devices cleared for the same intended use.

(See Comparison Table Below)

Comparison of Devices

	PREDICATES		PROPOSED	Similarities / Differences of Devices
	Atlantis Abutment for Dentsply Ankylos Implant	Inclusive Titanium Abutment Blanks	Inclusive Titanium Abutments, compatible with Dentsply Implants Ankylos C/X	
Manufacturer	Astra Tech	Prismatik	Prismatik	-
510(k) No.	K101004	K083192	K141923	-
Indications for Use	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 prosthesis, in the mandible or maxilla. The prosthesis can be cement or screw retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	The Inclusive Titanium Abutment Blank is intended to be used in conjunction with endosseous implants in the maxillary and/or mandibular arch to provide support for crowns, bridges or overdenture prostheses. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	Inclusive Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implant and are intended for use as an aid in prosthetic rehabilitation.	Same Intended Use
Dimensions of Abutment	11.5° Taper, 2.84 Gage Point	Cylinder Ø 9.43mm	Cylinder Ø 9.43mm 11.5° Taper, 2.84 Gage Point	Same
Abutment Screw	Integrated fastening screw (mobile, not removable)	Detached and removable	Detached and removable	Same
Platform Compatibility	Ankylos C/X 3.5mm, 4.5mm, 5.5mm, 7.0mm	Various (Straumann Bone Level, NobelActive, Branemark)	Ankylos C/X 3.5mm, 4.5mm, 5.5mm, 7.0mm	Same
Connection	Unigrip	Hexagon	Unigrip	Same
Material	Ti-6AL-4V ELI (ASTM F-136)	Ti-6AL-4V ELI (ASTM F-136)	Ti-6AL-4V ELI (ASTM F-136)	Same
Design / Construction	Machined	Machined	Machined	Same
Abutment Angle	0°-30°	0°-20°	0°-30°	Same
Implant Seat	Taper	Taper	Taper	Same
Screw Seat	Taper	Flat	Taper	Same