K121688

PRISMATIK
DENTALCRAFT, INC.

OCT 12 2012

510 (k) Summary

This 510 (K) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 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:	949-399-1940
Company FAX:	949-553-0924
Contact Person:	Armin Zehtabchi, (949) 225-1234 Kathleen Dragovich, (949) 399-1940
Date Summary Prepared:	October 9, 2012

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Multi-Unit Abutments with Angulations 17° and 30° for InclusiveTapered Implant System
21 CFR Reference:	21 CFR 872.3630
21 CFR Common Name:	Endosseous Dental Implant Abutment
Classification:	Class II
Panel:	Dental NHA

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:	Zimmer Dental Angled Tapered Abutment (K111853)

D. DEVICE DESCRIPTION

The Multi-Unit Abutments with Angulations 17° and 30° are available in multiple cuff heights to provide angulation correction for off-angle implant placement. The abutments are in the following sizes: 3.5mm Platform - Angled 17° - 2mmH and 3mmH, 3.5mm Platform – Angled 30° - 3mmH, 4.5mm Platform – Angled 17° - 2mmH, 3mmH, and 5mmH, 4.5mm Platform – Angled 30° - 3mmH and 5mmH.

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The abutment is secured to the implant with an abutment retaining screw. The abutment and abutment retaining screw are fabricated from titanium alloy. The tapered abutments facilitate multi-unit, screw-retained restoration, and are available in titanium 6AI-4V and will provide an angulation up to 30°.

The abutments are provided Sterile (Gamma) and are packaged in glass vials suspended by a carrier with a screw cap and is shrink wrapped. The glass vial is sealed inside a Chevron pouch that is compatible with radiation.

E. INDICATIONS FOR USE

Inclusive Multi-Unit Abutments are prosthetic components directly connected to endosseous dental implants and intended to provide support and retention for multi-unit screw-retained restorations. The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration. The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.

F. SUBSTANTIAL EQUIVALENCE

The Multi-Unit Abutments with Angulations 17° and 30° for Tapered Implant System are substantially equivalent to the Zimmer Dental Angled Tapered Abutment (K111853). These abutments are substantially equivalent in intended use, indication for use, material, design and performance.

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Comparison of Predicate Devices

Elements of Comparison	Prismatik's Multi-Unit Abutments with Angulations 17° and 30° for Tapered Implant System	Zimmer Dental Angled Tapered Abutment (K111853)
Material	Titanium	Titanium
Indications	Inclusive Multi-Unit Abutments are prosthetic components directly connected to endosseous dental implants and intended to provide support and retention for multi-unit screw-retained restorations. The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration. The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.	The Angled Tapered Abutment is used for a terminal or intermediate abutment for screw-retained multiple-unit restorations. The 3OAngled Tapered Abutment must be used within 45 degree of parallelism for a splinted restoration. The 15S0Angled Tapered Abutment must be used within **30** degrees of parallelism for a splinted restoration.
Abutment Angels	Up to 30°	Up to 30°
Platforms	3.5, 4.5mm	3.5, 4.5mm
Method of Attachment	Internal screw threaded through internal hex into implant	Internal screw threaded through internal hex into implant

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G. NON-CLINICAL TESTING

Non-clinical test data was used to support the decision of safety and effectiveness.

Non-clinical testing consisted of analysis of platforms to identify worst-case test samples and their performance in accordance with the FDA guidance Class II Special controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. The testing indicated that the device is safe and effective for its intended use and performed as well or better than the predicate device.

H. CONCLUSION

The information provided in the submission demonstrates that the Multi-Unit Abutments for Angulations 17° and 30° for Inclusive Tapered Implant System are substantially equivalent to the Zimmer Dental Angled Tapered Abutment (K111853).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 12 2012

Ms. Kathleen Dragovich
Manager, Regulatory Affairs/Quality Assurance
Prismatik Dentalcraft, Incorporated
2212 Dupont Drive, Suite P
Irvine, California 92612

Re: K121688
Trade/Device Name: Multi-Unit Abutments with Angulations 17° and 30 ° for Tapered Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 22, 2012
Received: August 27, 2012

Dear Ms. Dragovich:

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.

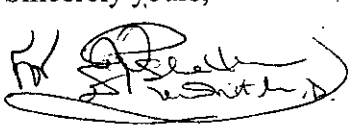
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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004-Indications for Use Statement

510 (K) Number (if known): To be determined

Device Name: Multi-Unit Abutments with Angulations 17° and 30° for Tapered Implant System

Indications for Use: Inclusive Multi-Unit Abutments are prosthetic components directly connected to endosseous dental implants and intended to provide support and retention for multi-unit screw-retained restorations. The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration. The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.

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 ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121688