PRISMATIK
DENTALCRAFT, INC.

K121391

DEC 10 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 IJK, Irvine, CA 92612
Company Phone:	(949) 225-1269
Company FAX:	949-553-0924
Primary Contact Person:	Armin Zehtabchi, (949) 225-1234
Secondary Contact Person	Marilyn Pourazar, (949) 225-1269
Date Summary Prepared:	December 5, 2012

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Inclusive Titanium Abutments for Camlog Screw-Line Implants
21 CFR Reference:	21 CFR 872.3630
21 CFR Common Name:	Endosseous Dental Implant Abutment
Classification:	Class II
Product Code:	NHA
Panel:	Dental

C. IDENTIFICATION OF PREDICATE DEVICE

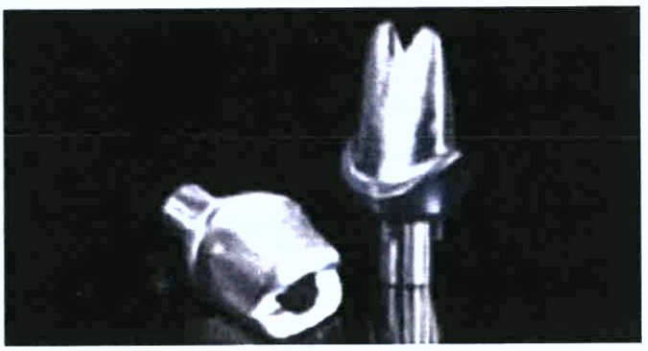
Trade/Proprietary Name:	CAMLOG Implant System Abutments (K073553)

DEVICE DESCRIPTION

The Inclusive® Titanium Abutments for Camlog Screw-Line Implants are endosseous implant abutments which are placed in to the dental implant to provide support for a prosthetic restoration. The subject abutments are indicated

for cemented restorations. These abutments are made of titanium grade Ti-6AL-4V ELI (meets ASTM Standard F-136). The abutment is placed over the implant shoulder and is mounted into the implant with a screw.

These abutments are compatible with the CAMLOG Screw-Line Implants as follows: 3.3mm, 3.8mm, 4.3mm, 5.0mm, and 6.0mm diameters.



D. **INDICATIONS FOR USE**

The Inclusive® Titanium Abutments for Camlog Screw-Line Implants are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the CAMLOG Screw-Line Implants in 3.3mm, 3.8mm, 4.3mm, 5.0mm, and 6.0mm diameters.

SUBSTANTIAL EQUIVALENCE

The Inclusive® Titanium Abutments for Camlog Screw-Line Implants are substantially equivalent to the CAMLOG Implant System Abutments (K073553). 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 Inclusive Titanium Abutments for Camlog Screw-Line Implants	CAMLOG Implant System Abutments (K073553)
Material	Ti -6AL-4V ELI	Ti -6AL-4V
Indications	The Inclusive® Titanium Abutments for Camlog Screw-Line Implants are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the CAMLOG Screw-Line Implants.	CAMLOG Implant System Abutments are intended to be used to fabricate crowns and bridges in conjunction with CAMLOG dental implants to support prostheses in the maxillary and/or mandibular arch.
Platform Diameters (mm)	3.3mm, 3.8mm, 4.3mm, 5.0mm, 6.0mm.	3.3mm, 3.8mm, 4.3mm, 5.0mm, 6.0mm.
Design	Implant/Abutment assembly with abutment screw. Abutment prosthetic connection to implant is 3 internal radial features.	Implant/Abutment assembly with abutment screw. Abutment prosthetic connection to implant is 3 internal radial features.
Performance	Fatigue testing in accordance with ISO 14971 - Dynamic fatigue test for endosseous dental implants conducted to validate mechanical compatibility with Camlog implants.	Substantially equivalent in indications and design to predicated devices determined to be substantially equivalent to pre-amendment devices.

E. NON-CLINICAL TESTING

Non-clinical test data was used to support the substantial equivalency.

The parameters of the abutment features that interface with the implant systems were determined by reverse engineering. The functionality of the abutments as well as their conformance to design input was further determined by laboratory mechanical testing. The following FDA's Guidance Document "Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments was used for the purpose of Implant to Abutment Compatibility. Static and fatigue tests were performed by following the ISO 14801: 2007- Dentistry — Implants —Dynamic fatigue test for endosseous dental implants. All testing conducted met the acceptance criteria and evaluated the worst case scenario. Performance testing data indicated the compatibility between implant/abutment. In addition, the sterilization validation/instructions by following the ANSI-AAMI ST79-2006: Comprehensive guide to steam sterilization and sterility assurance in health care facilities is provided in the Information for Use (IFU). Furthermore, the Prismatik's predicate device (K100993) is made of Titanium alloy.

F. CONCLUSION

The information provided in the submission demonstrates that the Inclusive® Titanium Abutments for Camlog Screw-Line Implants are substantially equivalent to the Camlog Implant System Abutments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 10, 2012

Mr. Armin Zehtabchi
Senior Regulatory Affairs / Quality Assurance Coordinator
Prismatik Dentalcraft, Incorporated
2212 Dupont Drive, Suite P
IRVINE CA 92612

Re: K121391
Trade/Device Name: Inclusive Titanium Abutment for Camlog Screw-Line Implants
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 5, 2012
Received: December 6, 2012

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 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,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K121391

Device Name: Inclusive Titanium Abutment for Camlog Screw-Line Implants

Indications for Use:

The Inclusive Titanium Abutments for Camlog Screw-Line Implants are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Camlog Screw-Line Implants in 3.3mm, 3.8mm, 4.3mm, 5.0mm and 6.0mm diameters.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.12.10 12:18:21 -05'00'

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

510(k) Number:_____