PRISMATIK DENTALCRAFT, INC.

K120858

DEC 0 6 2012

005-510 (k) Summary-807.92(c)

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. SUMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	2212 Dupont Dr., Suite IJK Irvine, CA 92612
Company Phone:	949-399-1940
Company FAX:	949-553-0924
Primary Contact Person:	Armin Zehtabchi, (949) 225-1234
Secondary Contact Person:	Marilyn Pourazar, (949) 225-1269
Date Summary Prepared:	November 28, 2012

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Inclusive® Implant Bridge Framework
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:.	Nobel /Procera Implant Bridge-K091848, Biomet 3i-CAM StructSure Overdenture Bars-K101582

D. DEVICE DESCRIPTION

Inclusive® Implant Bridge Framework attaches to implants. The Implant Bridge Framework is intended to be finished into a dental prosthesis using standard laboratory materials. The Inclusive® Implant Bridge Framework is customized by

following instructions and models specific to each patient.

The Inclusive® Implant Bridge Framework is made of titanium and shipped non-sterile. The Inclusive® Implant Bridge Framework will be attached with titanium screws.

E. INDICATION FOR USE

Indications for Use: The Inclusive® Implant Bridge Framework is indicated for use as a bridge framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

The Inclusive® Implant Bridge Framework is compatible with the following implant system: Nobel Biocare's Replace 3.5mm, 4.3mm, 5.0mm, and 6.0mm; Nobel Biocare's Branemark System 4.1mm; Nobel Biocare's Active 3.5mm and 4.3mm, Zimmer Dental Screw-Vent 3.5mm, 4.5mm, and 5.7mm; Biomet 3i Certain 3.4mm, 4.1mm, 5.0mm, and 6.0mm; Straumann Bone Level 4.1mm; Astra Tech OsseoSpeed 3.5mm and 4.5mm.

F. SUBSTANTIAL EQUIVALENCE

The Inclusive® Implant Bridge Framework is substantially equivalent to the Nobel /Procera Implant Bridge and Biomet 3i-CAM StructSure Overdenture Bars. The Inclusive® Implant Bridge Framework is substantially equivalent in indications for use, material, design and performance.

Comparison of Predicate Devices

Elements of Comparison	Prismatik's Inclusive® Implant Bridge Framework	Nobel /Procera Implant Bridge-K091848	Biomet 3i's CAM StructSure Overdenture Bars-K101582	Prismatik's Inclusive Mini Implant-K100932	Biomet 3i's CAM StructSure Precision Milled Bars-K080864
Material	Ti-6Al-4V ELI Alloy conforming to ASTM F 136.	Ti-6Al-4V ELI Alloy conforming to ASTM F 136.	Ti-6Al-4V ELI Alloy conforming to ASTM F 136.	Ti-6Al-4V ELI Alloy conforming to ASTM F 136.	Ti-6Al-4V ELI Alloy conforming to ASTM F 136.
Indications	The Inclusive® Implant Bridge Framework is indicated for use as a bridge framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.	The Nobel Procera Implant Bridge is indicated for use as a bridge framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.	The 3i Patient-Specific CAM StructSure® Precision Milled Bars are intended for use as an accessory to endosseous dental implan to support a prosthetic de in a partially or edentulo patient.	Inclusive® Mini Implants are self-tapping threaded titanium screws indicated for long-term applications. Inclusive® Mini Implants may also be used for provisional applications. These devices will allow immediate loading and long-term stabilization of dentures and provisional stabilization of dentures while standard implants heal.Jo be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.	The CAM StructSURE® Precision Milled Bars are intended for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw retained.
Design	Precision-milled bars made of titanium.	Precision-milled bars made of titanium. Design features and technological characteristics have been previously cleared for market (K091848).	Precision-milled bars made of titanium.Design features and technological characteristics have been previously cleared for market (K101582).	Precision-milled bars made of titanium.	Precision-milled bars made of titanium.
Performance	The titanium materials have sufficient mechanical strength for their indicated use.	Performance and technological characteristics have been previously cleared for market (K091848).	Performance and technological characteristics have been previously cleared for market (K101582).	The titanium materials have sufficient mechanical strength for their indicated use.	Performance and technological characteristics have been previously cleared for market (K0808864).

G. PERFORMANCE DATA

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. Various 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, and the safety and the effectiveness of the proposed device which meets the mechanical properties. In addition, the sterilization tests were validated by following the ANSI-AAMI ST79-2006: Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Furthermore, the use of Titanium alloy as a material with acceptable performance for Inclusive® Implant Bridge Framework is well documented in the dental literature.

H. COMPARISON OF TECHNOLOGICAL DIFFERENCES

There are no known technological differences between the Inclusive® Implant Bridge Framework and those of the predicate devices.

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 6, 2012

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

Re: K120858
Trade/Device Name: Inclusive® Implant Bridge Framework
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 16, 2012
Received: November 19, 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,

Kwame O. Ulmer for

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

004-Indications for Use Statement

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

Device Name: Inclusive® Implant Bridge Framework

Indications for Use: The Inclusive® Implant Bridge Framework is indicated for use as a bridge framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

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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 Runner DDS, MA 2012.12.06 13:40:31 -05'00'

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

510(k) Number: K120858