DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCtober 22, 2014

Prismatik Dentalcraft, Incorporated
Mr. Armin Zehtabchi
Senior Regulatory Affairs
2212 Dupont Drive, Suite P
Irvine, CA 92612

Re: K141211
Trade/Device Name: Inclusive® Titanium Abutments, compatible with Straumann® Standard Plus Tissue Level Implants
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: September 19, 2014
Received: September 22, 2014

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 contact 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. 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,

Erin I. Keith, M.S.
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): K141211

**Device Name**: Inclusive® Titanium Abutments, compatible with Straumann® Standard Plus Tissue Level Implants

**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 Straumann Standard Plus Tissue Level Implants in RN (4.1 mm and 4.8 mm) and WN (4.8 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<br>Irvine, CA 92612 |
| **Company Phone**: | (949) 225-1269 |
| **Company FAX:** | 949-553-0924 |
| **Primary Contact Person**: | Armin Zehtabchi, (949) 225-1234<br>*Senior RA* |
| **Secondary Contact Person**: | Marilyn Pourazar, (949) 225-1269<br>*Sr. Director, RA/QA* |
| **Date Summary Prepared**: | October 21, 2014 |

## B. DEVICE IDENTIFICATION

| | |
|---|---|
| **Trade/Proprietary Name**: | Inclusive® Titanium Abutments, compatible with Straumann® Standard Plus Tissue Level Implants |
| **Common Name**: | Endosseous Dental Implant Abutment |
| **Regulation Number**: | 872.3630 |
| **Product Code**: | NHA |
| **Device Class**: | II |
| **Review Panel**: | Dental |

## C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name: ITI synOcta Meso Abutments (K033243)
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 F136 Standard. They are compatible with Straumann Standard Plus Tissue Level Implants in RN (4.1 mm and 4.8 mm) and WN (4.8 mm) sizes. Abutments are to be provided straight and are not intended for any angulation correction.

| | **Inclusive Titanium Abutments, compatible with Straumann Standard Plus Tissue Level Implants** |
|---|---|
| Platform Compatibility | Straumann synOcta |
| Platform Diameter (mm) | RN 4.8 mm, WN 6.5 mm |
| Dimension of Abutment | Blank Abutment: 13.30 mm long, 9.44 mm diameter |
| Dimensions of Screw | 8 mm long, M2.0 thread |
| Connection | Octagonal |
| Material | Titanium Alloy *(ASTM F136)* |
| Design / Construction | Machined |
| Surface Treatment | None |
| Abutment Angle | Straight, 0° |
| Implant Seat | Sits on a Taper |
| Screw Seat | Sits on a Taper |

## 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 Straumann Standard Plus Tissue Level Implants in RN (4.1 mm and 4.8 mm) and WN (4.8 mm) sizes.

## F. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Inclusive Titanium Abutments, compatible with Straumann Standard Plus Tissue Level Implants, are substantially equivalent to the ITI synOcta Meso Abutments (K033243) and the Inclusive Titanium Abutment Blanks (K083192). They are substantially equivalent in intended use, materials, design, technological characteristics, and performance.

## COMPARISON OF DEVICES

| | PROPOSED | PREDICATE (I) | PREDICATE (II) | |
|---|---|---|---|---|
| | **Inclusive Titanium Abutments, compatible with Straumann Standard Plus Tissue Level Implants** | **Inclusive Titanium Abutment Blanks** | **ITI synOcta Meso Abutments** | **Similarities / Differences of Devices** |
| Manufacturer | Prismatik Dentalcraft | Prismatik Dentalcraft | Straumann USA | – |
| 510(k) Number | K141211 | K083192 | K033243 | – |
| 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.<br><br>Inclusive Titanium Abutments are compatible with Straumann Standard Plus Tissue Level Implants in RN (4.1 mm and 4.8 mm) and WN (4.8 mm) sizes. | 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. | Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The ITI synOcta Measo abutments are indicated for cemented restorations in esthetic areas of the mouth. The abutment can be used in single tooth replacements and multiple tooth restorations. | Same Intended Use |
| Platform Compatibility | Straumann synOcta | – | Straumann synOcta | Same |
| Platform Diameter (mm) | RN 4.8 mm<br>WN 6.5 mm | – | RN 4.8 mm<br>WN 6.5 mm | Same |
| Dimensions of Abutment Screw | 8 mm long<br>M2.0 thread | – | 8 mm long<br>M2.0 thread | Same |
| Connection | Octagonal | – | Octagonal | Same |
| Material (Abutment & Screw) | Titanium Alloy *(ASTM F136)* | Titanium Alloy *(ASTM F136)* | Abutment: Unalloyed Titanium *(ASTM F67)*<br>Screw: Titanium Alloy | Same with Predicate I. Similar with Predicate II. |
| Design / Construction | Machined | Machined | Machined | Same |
| Abutment Angle | 0° | 0°-20° | – | Similar |
| Implant Seat | Sits on a Taper | Sits on a Taper | Sits on a Taper | Same |
| Screw Seat | Sits on a Taper | Sits on a Taper | Sits on a Taper | Same |

## G. SUMMARY OF NON-CLINICAL TESTING/PERFORMANCE DATA

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 FROM THE NON-CLINICAL TESTING/ PERFORMANCE DATA

The results of the nonclinical testing performed, demonstrate that Inclusive Titanium Abutments compatible with Straumann Standard Plus Tissue Level Implants perform as well as the predicate devices. Therefore the proposed device is substantially equivalent with the predicate devices cleared for the same intended use.