Institut Straumann AG
% Jennifer Jackson
Director of Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K162848
Trade/Device Name: Straumann® CARES® Golden Ti/TiN Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 25, 2017
Received: August 28, 2017

Dear Jennifer Jackson:

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,

Mary S. Runner -S
Tina Kiang, Ph.D.
Acting 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

K162848

Device Name

Straumann® CARES® Golden Ti/TiN Abutments

Indications for Use (Describe)

Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges or overdentures.

The Straumann CARES Golden Ti/TiN Abutments are indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration is cement-retained.

Type of Use (Select one or both, as applicable)

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
5. **510(k) Summary**

**Submitter:** Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810

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**Prepared By & Secondary Contact:**
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Institut Straumann AG
+41 61 965 1260

**Date Prepared:** September 22, 2017

**Product Code(s):** NHA (21 CFR 872.3630)

**Device Class:** II (21 CFR 872.3630)

**Classification Panel:** Dental

**Classification Name:** Endosseous dental implant abutment (21 CFR 872.3630)

**Proprietary Name:** Straumann® CARES® Golden Ti/TiN Abutment

**Primary Predicate Device:**
K082764, Straumann CARES WN Ti Abutments (Institut Straumann)

**Reference Device(s):**
K052272, Straumann CARES RN Ti Abutments (Institut Straumann)
K072151, Straumann CARES RC Ti Abutments (Institut Straumann)
K081005, Straumann CARES NC Ti Abutments (Institut Straumann)
K992334, 3i TiN Coated Implants and Abutments (Implants Innovations, Incorporated (3i))

**Device Description:** The previously cleared Straumann CARES Titanium Abutments are placed onto dental implants to support prosthetic reconstructions such as crowns and bridges. The abutment allows for individual customization regarding function and esthetics. The design step is typically performed by the dental laboratory to the specifications from a clinician. The abutments are produced by a Straumann Manufacturing milling center.
The patient-specific abutment is designed by a traditional wax-up and subsequent scanning or by scanning of the intraoral setting and designing the element via CAD software. The design information is sent via an Internet portal to Straumann. Straumann verifies the design against the validated design parameters. These design limits include a maximum angulation of 30° and a minimum surface area as follows:

<table>
<thead>
<tr>
<th>Tooth Position</th>
<th>Minimum surface area mm²</th>
</tr>
</thead>
<tbody>
<tr>
<td>7,10, 24,25</td>
<td>37</td>
</tr>
<tr>
<td>4,5,12,13,20,21,28,29</td>
<td>47</td>
</tr>
<tr>
<td>26,11,2,27,8,9</td>
<td>43</td>
</tr>
<tr>
<td>1-3, 14-16, 17,19,30-32</td>
<td>56</td>
</tr>
</tbody>
</table>

The abutments are manufactured from solid grade 4 titanium at the Straumann milling center. The abutment is delivered to the dental laboratory for final processing before delivery to the clinician. The abutments are attached to the implant with a titanium alloy basal screw. The occlusal restoration is affixed to the titanium abutment using dental cement.

The proposed devices are a modification of the previously licensed devices. The titanium abutments that serve as the base of the CARES Golden Ti/TiN Abutments (the uncoated abutments) are identical in every respect to the reference devices. The modification consists of the addition of a titanium nitride (TiN) coating on the emergence profile and coronal aspect of the abutment. The apical portion of the abutment consisting of the implant-to-abutment interface is masked during the coating process to assure that the interface remains uncoated.

**Indications For Use:** Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges or overdentures.

The Straumann CARES Golden Ti/TiN Abutments are indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration is cement-retained.

**Materials:** The substrate material for all Straumann CARES Golden Ti/TiN Abutments is commercially pure Titanium (grade 4) conforming to ISO 5832-2. The surface of the emergence profile and coronal aspect of the abutments are coated with titanium nitride (TiN). The implant-to-abutment interface is masked and remains uncoated.
Technological Characteristics: A comparison of the relevant technological characteristics between the subject and primary predicate devices is provided in the table that follows.

Performance Data: Test data to support the evaluation of the subject Straumann CARES Golden Ti/TiN abutments is as follows:

- Sterilization validation in accordance with ISO 17665-1 and ISO/TS 17665-2
- Biocompatibility assessment per ISO 10993-1
- Cytotoxicity testing per ISO 10993-5
- Chemical characterization per ISO 10993-18
- Dynamic fatigue testing per ISO 14801 by reference to K052272, K072151, K081005 and K082764
- Coating characterization including chemical composition, thickness, porosity, mean volume percent voids, SEM images at 100X
- Adhesion testing by static shear bonding strength per ASTM F1044 employing minimum shear stress acceptance criteria per ASTM F2068
- Adhesion testing by dynamic shear bonding strength per ASTM F1160
- Abrasion testing consistent with the method described by Tamura, et al, entitled Mechanical Properties of Surface Nitrided Titanium for Abrasion Resistant Implant Materials.

No animal or human clinical studies were conducted.

Conclusions: Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.
<table>
<thead>
<tr>
<th>Feature</th>
<th>Primary Predicate Devices</th>
<th>Subject Devices</th>
<th>Equivalence Discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CARES Titanium Abutments (K082764)</td>
<td>CARES Titanium Gold Abutments</td>
<td></td>
</tr>
<tr>
<td>Indications For Use</td>
<td>Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges and overdentures. The Straumann Titanium Abutment is indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration is cement-retained.</td>
<td>Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges or overdentures. The Straumann CARES Golden Ti/TiN Abutment is indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration is cement-retained.</td>
<td>Identical</td>
</tr>
<tr>
<td>Compatible Implants</td>
<td>Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the NN, RN and WN implant-to-abutment interface geometries.</td>
<td>Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the NN, RN and WN implant-to-abutment interface geometries.</td>
<td>Identical</td>
</tr>
<tr>
<td>Material</td>
<td>Commercially pure grade 4 Titanium per ISO 5832-2</td>
<td>Commercially pure grade 4 Titanium per ISO 5832-2</td>
<td>Identical</td>
</tr>
<tr>
<td>Surface Finish</td>
<td>Uncoated (raw titanium)</td>
<td>Titanium nitride (TiN) coating on emergence profile and coronal surfaces</td>
<td>Equivalent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>The TiN coating is being added to impart gold color to the emergence profile and coronal surfaces of the abutment in order to improve the esthetics of the finished restoration. The presence of the coating does not change the intended uses or indications of the devices. This use of TiN coating was originally cleared to market per K992334.</td>
</tr>
<tr>
<td>Construction</td>
<td>One-piece solid devices.</td>
<td>One-piece solid devices.</td>
<td>Identical</td>
</tr>
</tbody>
</table>
## Design Limits:

<table>
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<th>Subject Devices</th>
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<td>CARES Titanium Abutments  (K082764)</td>
<td>CARES Titanium Gold Abutments</td>
<td></td>
</tr>
<tr>
<td>Maximum Angulation:</td>
<td>30°</td>
<td>30°</td>
<td>Identical</td>
</tr>
<tr>
<td>Minimum Surface Area:</td>
<td>37 mm²</td>
<td>37 mm²</td>
<td></td>
</tr>
<tr>
<td>Pos, 7,10, 24,25</td>
<td></td>
<td></td>
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<tr>
<td>Pos, 4,5,12,13,20,21,28,29</td>
<td>47 mm²</td>
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<td>43 mm²</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pos, 1-3, 14-16, 17-19,30-32</td>
<td>56 mm²</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Packaging

- The abutment and basal screw in reclosable poly bags, co-packaged in a kraft board box.
- The abutment and basal screw in reclosable poly bags, co-packaged in a kraft board box.

## Sterility

- Provided non-sterile.
  Terminally sterilized via moist heat (autoclave) to a Sterility Assurance Level of 10^-6. Validated per ISO 17665-1.
- Provided non-sterile.
  Terminally sterilized via moist heat (autoclave) to a Sterility Assurance Level of 10^-6. Validated per ISO 17665-1.