March 8, 2017

Straumann USA, LLC
% Jennifer Jackson
Director, Regulatory Affairs & Quality
60 Minuteman Road
Andover, Massachusetts 01810

Re: K162890
Trade/Device Name: Straumann Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 16, 2017
Received: February 17, 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,

Lori A. Wiggins -S

for
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

510(k) Number (if known)
K162890

Device Name
Straumann® Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments

Indications for Use (Describe)

Straumann® Bone Level Tapered Implants Ø2.9 mm are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and aesthetic oral rehabilitation of patients with missing teeth. Straumann® Bone Level Tapered Implants Ø2.9 mm can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth or multiple-tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding components (abutments). The Straumann® Bone Level Tapered Implants Ø2.9 mm are indicated for reconstruction of missing incisors in the lower jaw and lateral incisors in the upper jaw.

Straumann® Closure Caps and Healing Abutments are indicated to be placed in the dental implant after placement in the patient’s jaw to protect the inner configuration of the implant and to form, maintain and stabilize the soft tissue during the healing process. Closure Caps and Healing Abutments should be used only with the corresponding implant connection.

Straumann® SC Temporary Abutments are indicated for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. Straumann® SC Temporary Abutments have a maximum duration of usage of 180 days.

Straumann® SC Variobase® abutments are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented on the Straumann® SC Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. All digitally designed copings and/or crowns for use with the Straumann® Variobase® Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

Straumann® SC CARES® abutments are indicated for single-tooth replacements and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained.

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

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED
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510(k) Summary

5.1 Submitter’s Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road
Andover, MA 01810

Phone Number: 1-978-747-2509
Fax Number: 1-978-747-0023
Contact Person: Jennifer M. Jackson, MS
Date of Submission: March 6, 2017

5.2 Name of the Device

Trade Names: Straumann® Ø2.9 mm Bone Level Tapered Implants
SC Closure Cap
SC Healing Abutments
SC Temporary Abutments
SC Variobase® Abutments
SC CARES® Abutments

Common Name: Endosseous Dental Implant
Endosseous Dental Implant Abutment

Classification Name: Endosseous Dental Implant
Regulation Number: §872.3640
Classification: Class II
Product Codes: DZE, NHA

5.3 Predicate Device(s)

Primary Predicate:
K140878 – Straumann Bone Level Tapered Implant
Traditional 510(k) Submission

Straumann® Ø2.9 mm Bone Level Tapered Implants

510(k) Summary

Reference Devices:
K120414 – OsseoSpeed™ Plus
K130808 – Straumann Healing Abutments, Healing Caps, and Closure Screws
K092814 – Straumann NC Temporary Abutments
K120822 – Straumann CARES Variobase Abutments
K142890 – Straumann Variobase Abutments
K150203 – Medentika CAD/CAM Abutments
K150899 – Straumann CARES TAN Abutments
K062129 – P.004 Implants

5.4 Device Description

The Straumann Ø2.9mm Bone Level Tapered (BLT) Implants are apically tapered implants with an external diameter of Ø2.9 mm and lengths of 10 mm, 12 mm, and 14 mm. The implants are manufactured utilizing the Roxolid material and are finished with either the SLA® or SLActive® surface. The prosthetic platform is identified as SC (Small CrossFit®) which corresponds to a shoulder diameter of Ø2.9 mm.

The closure cap and healing abutments are manufactured from Titanium Grade 4 and are anodized blue for identification purposes. The closure cap is conical and has a height of 0.5 mm. The healing abutments are seated in the implant with a basal screw which is manufactured from TAN. The healing abutments are oval in shape and are available in four different heights ranging between 2.0 mm and 6.5 mm.

The temporary abutments are manufactured from TAN and are anodized blue for identification purposes. The temporary abutments are oval in shape in order to accommodate narrow interdental spaces and are available with three different gingival heights ranging between 1.0 mm and 3.0 mm. The temporary abutments are seated in the implant with a basal screw which is also manufactured from TAN.

There are three components to the Straumann® SC Variobase™ Abutments:

- Straumann® SC Variobase™ Abutments (Ti-base)
- Prosthetic restoration (coping and/or crown)
- Basal Screw
The Straumann® SC Variobase® Abutments are manufactured from TAN. The abutments are oval in shape to accommodate narrow interdental spaces and are available with three different gingival heights ranging between 1.0 mm and 3.0 mm. The abutments will be delivered with the corresponding basal screw.

The following is an overview of the possible prosthetic restoration (coping and/or crown) materials:

- Cast materials:
  - Type 4 metals (ISO 22674)
  - Base metal alloys (e.g., cobalt-chromium (CoCr))
  - Noble metal alloys (e.g., gold alloy)

- Press materials:
  - IPS e.max® Press Ceramic (K120053)

- Digital materials:
  - coron®
  - zerion® LT
  - polycon® ae

All digitally designed copings and/or crowns for use with the Straumann® Variobase® Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

The Straumann® SC CARES® Abutments are customized abutments manufactured from TAN. The abutments are designed by the customer by scanning the intraoral situation and designing of the shape with the CAD module of the integrated software. The design data is then sent to Straumann where the fabrication of the customized abutment is performed. The TAN alloy is capable of being directly veneered once the abutment is subject to a heat treatment step by the dental laboratory technician. A finished crown may also be cemented to the subject abutments rather than by direct veneer. The abutments will be delivered with the corresponding basal screw.
5.5 Intended Use

The Straumann dental Implants are intended for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of patients with missing teeth.

Closure Caps and Healing Abutments are intended for use with the Straumann® Bone Level Tapered Implants Ø2.9 mm to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.

Straumann® SC Temporary Abutments are intended to be placed into Straumann dental implants to provide support for temporary crowns and bridges.

Straumann® SC Variobase® Abutments are intended to be placed into Straumann® Bone Level Tapered Implants Ø2.9 mm to provide support for individual crowns or bridges.

Straumann® SC CARES® abutments are intended for use as an aid in prosthetic rehabilitation.

5.6 Indications for Use

Straumann® Bone Level Tapered Implants Ø2.9 mm are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and aesthetic oral rehabilitation of patients with missing teeth. Straumann® Bone Level Tapered Implants Ø2.9 mm can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth or multiple-tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding components (abutments).

The Straumann® Bone Level Tapered Implants Ø2.9 mm are indicated for reconstruction of missing incisors in the lower jaw and lateral incisors in the upper jaw.

Straumann® Closure Caps and Healing Abutments are indicated to be placed in the dental implant after placement in the patient’s jaw to protect the inner configuration of the implant and to form, maintain and stabilize the soft tissue during the healing process. Closure Caps and Healing Abutments should be used only with the corresponding implant connection.
Straumann® SC Temporary Abutments are indicated for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. Straumann® SC Temporary Abutments have a maximum duration of usage of 180 days.

Straumann® SC Variobase® abutments are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented on the Straumann® SC Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. All digitally designed copings and/or crowns for use with the Straumann® Variobase® Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

Straumann® SC CARES® abutments are indicated for single-tooth replacements and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained.

### 5.7 Technological Characteristics

#### 5.7.1 Straumann® Ø2.9 mm Bone Level Tapered Implants

The technological principles are the same for the subject and primary predicate devices. Both the subject device and primary predicate device are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and aesthetic oral rehabilitation of patients with missing teeth. The subject devices are specifically indicated for the lateral incisor in the upper jaw and the lower incisors. The indications for use for the subject devices are within the scope of the indications for use for the primary predicate device. The narrower indications do not change the intended use.

The main differences in the technological characteristics between the subject device and the primary predicate device are the implant diameter (Ø2.9 mm vs. Ø3.3, Ø 4.1 and Ø 4.8 mm) and the implant to abutment connection (Small CrossFit® (SC) versus Narrow CrossFit® (NC) and Regular CrossFit® (RC)). The technological characteristics of the subject devices are compared to the primary and reference predicate in Table 1.
Traditional 510(k) Submission

Straumann® Ø2.9 mm Bone Level Tapered Implants

510(k) Summary

<table>
<thead>
<tr>
<th>FEATURE</th>
<th>PROPOSED DEVICE</th>
<th>PRIMARY PREDICATE DEVICE</th>
<th>REFERENCE PREDICATE DEVICE</th>
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<td>K Number</td>
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<td>K120414</td>
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<td>Titanium-13 Zirconium alloy (Roxolid®)</td>
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<td>SLA® and SLActive®</td>
<td>OsseoSpeed™</td>
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<td>Narrow CrossFit® (NC)</td>
<td>Six position connection</td>
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<tr>
<td>Implant Diameter</td>
<td>Ø2.9 mm</td>
<td>Ø3.3, Ø4.1, and Ø4.8 mm</td>
<td>Ø3.0 mm</td>
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<tr>
<td>Implant Length</td>
<td>10, 12, and 14 mm</td>
<td>8, 10, 12, and 14 mm</td>
<td>8, 9, 11, 13, and 15 mm</td>
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<tr>
<td>Implant Design</td>
<td>Straight implant with apical taper</td>
<td>Straight implant with apical taper</td>
<td>Straight implant with apical taper</td>
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</table>

Table 1 – Comparison of subject device versus primary and reference predicate devices
(Dental Implants)

5.7.2 Straumann® Closure Cap and Healing Abutments

The technological principles and intended use are identical for the subject and reference predicate devices. The intended use is to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. The main differences in the technological characteristics between the subject and reference predicate devices are the shape and diameter of the devices. The subject devices are dimensionally smaller to accommodate the smaller diameter implant. The technological characteristics of the subject devices are compared to the reference predicate in Table 2.
Traditional 510(k) Submission
Straumann® Ø2.9 mm Bone Level Tapered Implants

510(k) Summary

<table>
<thead>
<tr>
<th>FEATURE</th>
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<tr>
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<td>Small CrossFit® (SC)</td>
<td>Narrow CrossFit® (NC)</td>
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<td>Diameter or Minor Oval Dimension/Major Oval Dimension</td>
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<td></td>
<td>Closure Cap:</td>
<td>Closure Cap:</td>
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<td></td>
<td>Ø2.4 mm</td>
<td>Ø2.77 and Ø3.05 mm</td>
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<td>Healing Abutments:</td>
<td>Healing Abutment:</td>
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<tr>
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<td>3.3/4.3 mm</td>
<td>Ø3.6</td>
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<td>3.6/5.0 mm</td>
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<td>Overall Length</td>
<td>Closure Cap:</td>
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<td>5.8 mm</td>
<td>6.25 and 6.8 mm</td>
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<td>7.0, 8.5, 10.0, 11.5 mm</td>
<td>8.1, 9.6, 11.1 mm</td>
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<td>Gingival Heights</td>
<td>Closure Cap:</td>
<td>Closure Cap:</td>
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<td>0.5 mm</td>
<td>0 mm and 0.5 mm</td>
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<td>Healing Abutments:</td>
<td>Healing Abutments:</td>
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<tr>
<td></td>
<td>2.0, 3.5, 5.0 and 6.5 mm</td>
<td>2.0, 3.5, and 5.0 mm</td>
</tr>
</tbody>
</table>

Table 2 – Comparison of subject device versus reference device (SC Closure Cap and SC Healing Abutments)

5.7.3 Temporary Abutments

The technological principles and intended use are identical for the subject and reference predicate devices. The devices are intended to be placed into Straumann dental implants to provide support for temporary crowns and bridges. The main differences in the technological characteristics between the subject and reference predicate devices are the shape and diameter of the devices. The subject devices are dimensionally smaller to accommodate the smaller diameter implant. The technological characteristics of the subject devices are compared to the reference predicate in Table 3.
Traditional 510(k) Submission

Straumann® Ø2.9 mm Bone Level Tapered Implants

510(k) Summary

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<td>Narrow CrossFit® (NC)</td>
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<td>Major Oval Dimension</td>
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<td>Gingival Heights</td>
<td>1.0, 2.0, and 3.0 mm</td>
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</table>

Table 3 – Comparison of subject device versus reference predicate device (SC Temporary Abutments)

5.7.4 SC Variobase® Abutments

The technological principles and intended use are identical for the subject and reference predicate devices. The devices are intended to be placed into dental implants to provide support for individual crowns or bridges. The subject devices are specifically indicated for the lateral incisor in the upper jaw and the lower incisors. The indications for use for the subject devices are within the scope of the indications for use for the reference predicate devices. The narrower indications do not change the intended use.

The main differences in the technological characteristics between the subject and reference predicate devices are the shape and diameter of the devices. The subject devices are dimensionally smaller to accommodate the smaller diameter of the implant. The subject devices also have only two retention features compared to the Straumann reference predicate device which has four retention features. The Medentika reference predicate has one retention feature. The technological characteristics of the subject devices are compared to the reference predicate in Table 4.
## Traditional 510(k) Submission

### Straumann® Ø2.9 mm Bone Level Tapered Implants

#### 510(k) Summary

<table>
<thead>
<tr>
<th>FEATURE</th>
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<td><strong>Diameter or Minor Oval Dimension/ Major Oval Dimension</strong></td>
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<td>Ø3.8 – 7.0 mm</td>
<td>Ø3.5 – 5.7 mm</td>
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<td><strong>Overall Abutment Height</strong></td>
<td>6.7 – 8.7 mm</td>
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<td>6.15 – 7.54 mm</td>
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<td><strong>Coping/ Crown Material</strong></td>
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<td><strong>Traditional Workflow:</strong> Type 4 metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: IPS e.max® CAD Ceramic (permanent) coron® (permanent) zeron® (permanent) polycon® ae (temporary)</td>
<td><strong>Digital Workflow:</strong> zeron® (permanent)</td>
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<td><strong>Design Workflow</strong></td>
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<td>Wax-up or Open CAD CARES® Visual</td>
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<td><strong>Manufacturing Workflow</strong></td>
<td>Traditional casting or pressing or Straumann Milling</td>
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<td><strong>Mode of Action</strong></td>
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</table>

Table 4 – Comparison of subject device versus reference device (SC Variobase Abutments)

### 5.7.5 SC CARES® Abutments

The technological principles and intended use are identical for the subject and reference predicate devices. The devices are intended for use as an aid in prosthetic rehabilitation. The main differences in the technological characteristics between the subject and reference predicate devices are the diameter and the dimension for the abutment to implant connection. The technological characteristics of the subject devices are compared to the reference predicate in Table 5.
Traditonal 510(k) Submission

Straumann® Ø2.9 mm Bone Level Tapered Implants

510(k) Summary

<table>
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<td>Implant to Abutment</td>
<td>Small CrossFit® (SC)</td>
<td>Narrow CrossFit® (NC)</td>
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<tr>
<td>Connection</td>
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<tr>
<td>Abutment coronal design</td>
<td>CAD CAM design process. Designs controlled by material-specific design limits in the CARES Visual CAD software, model verification performed by the CAM software and milling blank dimensions used by the Straumann milling center.</td>
<td>CAD CAM design process. Designs controlled by material-specific design limits in the CARES Visual CAD software, model verification performed by the CAM software and milling blank dimensions used by the Straumann milling center.</td>
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<td>CAD Design Limits</td>
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</table>

Table 5 – Comparison of subject device versus reference device (SC CARES Abutments)

5.8 Performance Testing

The following performance data were provided in support of the substantial equivalence determination.

5.8.1 Sterilization Validation

The sterilization process for the SC Temporary Abutments, SC Variobase Abutments, and SC CARES Abutments as recommended in the labeling was validated according to applicable recommendations in the FDA guidance document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015”.

5.8.2 Biocompatibility Testing

The subject devices have the identical nature of body contact, contact duration, material formulation, manufacturing processes, and sterilization methods compared to the primary and reference predicate devices. No new issues of biocompatibility are raised for the subject devices. Therefore, no additional biocompatibility testing was required.

5.8.3 Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided according to the FDA guidance documents “Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations” and “General Principles of Software Validation; Final Guidance for Industry and FDA Staff”. The software for this device was considered as a “moderate” level of concern as a failure in the Straumann CARES Visual software could result in a non-fitting or poor-fitting restoration or framework.

5.8.4 Bench Testing
Dynamic fatigue, static strength, and insertion torque tests were conducted according to the FDA guidance document “Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments” and demonstrated the Straumann® Ø2.9 mm Bone Level Tapered implants, SC Temporary Abutments, SC Variobase Abutments, and SC CARES abutments are equivalent to the predicate and reference devices.

5.9 Conclusion
The documentation submitted in this premarket notification demonstrates the Straumann® Ø2.9 mm Bone Level Tapered implants, SC Closure Caps and Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, and SC CARES Abutments are substantially equivalent to the primary predicate and reference devices.