December 8, 2020

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

Re: K201711
Trade/Device Name: CARES® Screw - Retained Bars and Bridges (SRBB)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 5, 2020
Received: November 9, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew Steen
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K201711

Device Name:

CARES® Screw - Retained Bars and Bridges (SRBB)

Indications for Use *(Describe)*

CARES® Screw-retained Bridges and Bars are indicated for use as bars and bridges that attach to implants to provide support for prosthetic reconstructions such as bridges and overdentures. The final processed products have the purpose of restoring chewing function. CARES® Screw-retained Bridges and Bars are indicated for screw-retained restorations.

CARES® Screw - Retained Bars and Bridges are designed to interface with the following dental implant systems (Implant System Compatibility / Series / Implant diameter (mm) / Platform diameter (mm)):

Nobel Biocare Replace Select / E-Series / Diameters 3.5, 4.3, 5.0, 6.0 / Platform 3.5, 4.3, 5.0, 6.0
Dentsply Implants - ASTRA TECH OsseoSpeed EV / EV-Series / 3.0, 3.6, 4.2, 4.8, 5.4 / Platform 3.0, 3.6, 4.2, 4.8, 5.4
Nobel Biocare NobelActive / F-Series / Diameter 3.0, 3.5, 4.3, 5.0 / Platform 3.0, 3.5, 3.9 (4.3), 3.9 (5.0)
Neodent - Grand Morse / GM Series / Diameters 3.5, 3.75, 4.0, 4.3, 5.0, 6.0 / Platform 3.0
Biomet 3i - Certain / H-Series / Diameter 3.25, 4.0, 5.0 / Platform 3.4, 4.1, 5.0
Biomet 3i – External Hex / I-Series / Diameter 3.25, 3.75, 4.0, 5.0 / Platform 3.4, 4.1, 5.0
Nobel Biocare - Brånemark System / K-Series / Diameter 3.3, 3.75, 4.0, 5.0 / Platform 3.5, 4.1, 4.1, 5.1
Zimmer Dental Tapered Screw-vent / R-Series / Diameter 3.3, 3.7, 4.1, 4.7, 6.0 / Platform 3.5, 4.5, 5.7
Dentsply Implants - ASTRA TECH OsseoSpeed TX / S-Series / Diameter 3.5, 4.0, 4.5, 5.0 / Platform 3.5, 4.0, 4.5, 5.0
Dentsply Implants – XiVE S / T- Series / Diameter 3.4, 3.8, 4.5, 5.5 / Platform 3.4, 3.8, 4.5, 5.5

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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# 5 510(k) Summary

## 5.1 Submitter's Contact Information


| | |
|---|---|
| Submitter: | Straumann USA, LLC<br>60 Minuteman Road<br>Andover, MA 01810<br>Registration No.: 1222315 Owner/Operator No.: 9005052<br><br>On the behalf of:<br><br>Medentika GmbH<br>Hammweg 8-10<br>76549 Hügelsheim, Germany<br>Registration No.: 3008770646 Owner/Operator No.: 10034561 |
| Contact Person: | Jennifer M. Jackson, MS<br>Director of Regulatory Affairs and Quality<br>Phone Number: +1-978-747-2509<br>Email: jennifer.jackson@straumann.com |
| Prepared By & Alternate Contact: | Olivier Russo<br>Regulatory Affairs and Compliance Manager<br>Institut Straumann AG<br>Phone number: +41 61 965 1260 |
| Date Prepared: | December 8, 2020 |


## 5.2 Name of the Device

| | |
|---|---|
| Trade Names: | CARES® Screw - Retained Bars and Bridges (SRBB) |
| Common Name: | CARES® Screw - Retained Bars and Bridges |
| Classification Name: | Abutment, Implant, Dental, Endosseous |
| Regulation Number: | 21 CFR 872.3630 |
| Device Classification: | II |
| Product Code(s): | NHA |
| Classification Panel: | Dental |

## 5.3 Predicate Device(s)

Primary Predicate:

- K190097 – Straumann CARES® Screw-Retained Bridges and Bars

Reference Devices:

- K170838 – Medentika CAD/CAM TiBases
- K180536 – Neodent GM (Grand Morse) implant Line
- K120414 – OsseoSpeed™ Plus
- K180564 – MRI Safety Information Labeling Change
- K150203 – Medentika CAD/CAM Abutments

## 5.4 Device Description

The CARES® Screw Retain Bars and Bridges, referenced in Table 1, are used for the restoration of different dental implants systems with different endosteal diameters, lengths and platforms. The bars and bridges presented in the premarket notification submission (identified as “SRBB” for Screw Retained Bridges and Bars) are designed to interface with different implant connections. They allow for individual customization regarding function and esthetics. They attach directly to dental implants. The devices are intended to be finished into a bridge or overdenture using standard dental laboratory techniques and materials. Screw Retained Bars and Bridges (SRBB) devices facilitate customization to meet the functional and esthetic requirements of the individual patient. They are patient-specific medical devices, i.e. they are designed by a dental professional (clinician or dental technician) and fabricated by Medentika specifically for an individual patient. SRBB devices are designed via Computer Aided Design (CAD). After importing a scan of the patient model, Commercial Off-The-Shelf (COTS) Software includes the ability to generate digital restoration models incorporating the subject devices. The digital restoration model is transferred to the milling center where the restoration is produced using Computer Aided Manufacturing (CAM)-techniques. The devices are made entirely of titanium Grade 5 according to ASTM F136, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*.

# K201711 – Traditional 510(k)

# CARES® Screw - Retained Bars and Bridges (SRBB)

510(k) Summary

| Reference | Product Description | BRIDGE / BAR SYSTEM |
|---|---|---|
| CR 12000 | CARES® s-ret bridge, TAV, 2 elements | BRIDGE |
| CR 12001 | CARES® s-ret bridge, TAV, 3 elements | |
| CR 12002 | CARES® s-ret bridge, TAV, 4 elements | |
| CR 12003 | CARES® s-ret bridge, TAV, 5 elements | |
| CR 12004 | CARES® s-ret bridge, TAV, 6 elements | |
| CR 12005 | CARES® s-ret bridge, TAV, 7 elements | |
| CR 12006 | CARES® s-ret bridge, TAV, 8 elements | |
| CR 12007 | CARES® s-ret bridge, TAV, 9 elements | |
| CR 12008 | CARES® s-ret bridge, TAV, 10 elements | |
| CR 12009 | CARES® s-ret bridge, TAV, 11 elements | |
| CR 12010 | CARES® s-ret bridge, TAV, 12 elements | |
| CR 12011 | CARES® s-ret bridge, TAV, 13 elements | |
| CR 12012 | CARES® s-ret bridge, TAV, 14 elements | |
| CR 12013 | CARES® s-ret bridge, TAV, 15 elements | |
| CR 12014 | CARES® s-ret bridge, TAV, 16 elements | |
| CR 12015 | CARES® Basic Bar, TAV, 2 Impl. | BASIC BAR |
| CR 12016 | CARES® Basic Bar, TAV, 3 Impl. | |
| CR 12017 | CARES® Basic Bar, TAV, 4 Impl. | |
| CR 12018 | CARES® Basic Bar, TAV, 5 Impl. | |
| CR 12019 | CARES® Basic Bar, TAV, 6 Impl. | |
| CR 12020 | CARES® Basic Bar, TAV, 7 Impl. | |
| CR 12021 | CARES® Basic Bar, TAV, 8 Impl. | |
| CR 12022 | CARES® Basic Bar, TAV, 9 Impl. | |
| CR 12023 | CARES® Basic Bar, TAV, 10 Impl. | |
| CR 12024 | CARES® Advanced Bar, TAV, 2 Impl. | ADVANCED BAR |
| CR 12025 | CARES® Advanced Bar, TAV, 3 Impl. | |
| CR 12026 | CARES® Advanced Bar, TAV, 4 Impl. | |
| CR 12027 | CARES® Advanced Bar, TAV, 5 Impl. | |
| CR 12028 | CARES® Advanced Bar, TAV, 6 Impl. | |
| CR 12029 | CARES® Advanced Bar, TAV, 7 Impl. | |
| CR 12030 | CARES® Advanced Bar, TAV, 8 Impl. | |
| CR 12031 | CARES® Advanced Bar, TAV, 9 Impl. | |
| CR 12032 | CARES® Advanced Bar, TAV, 10 Impl. | |
| CR 12033 | CARES® Complex Bar, TAV, 2 Impl. | COMPLEX BAR |
| CR 12034 | CARES® Complex Bar, TAV, 3 Impl. | |
| CR 12035 | CARES® Complex Bar, TAV, 4 Impl. | |
| CR 12036 | CARES® Complex Bar, TAV, 5 Impl. | |
| CR 12037 | CARES® Complex Bar, TAV, 6 Impl. | |
| CR 12038 | CARES® Complex Bar, TAV, 7 Impl. | |
| CR 12039 | CARES® Complex Bar, TAV, 8 Impl. | |
| CR 12040 | CARES® Complex Bar, TAV, 9 Impl. | |
| CR 12041 | CARES® Complex Bar, TAV, 10 Impl. | |

**Table 1 – Listing of devices**

## 5.5 Intended Use

CARES® Screw-retained Bars and Bridges are prosthetic components directly connected to the endosseous dental implant as an aid in prosthetic rehabilitations.

## 5.6 Indications for Use

CARES® Screw-retained Bridges and Bars are indicated for use as bars and bridges that attach to implants to provide support for prosthetic reconstructions such as bridges and overdentures. The final processed products have the purpose of restoring chewing function. CARES® Screw-retained Bridges and Bars are indicated for screw-retained restorations.

CARES® Screw - Retained Bars and Bridges are designed to interface with the following dental implant systems (Implant System Compatibility / Series / Implant diameter (mm) / Platform diameter (mm)):

Nobel Biocare Replace Select / E-Series / Diameters 3.5, 4.3, 5.0, 6.0 / Platform 3.5, 4.3, 5.0, 6.0

Dentsply Implants - ASTRA TECH OsseoSpeed EV / EV-Series / 3.0, 3.6, 4.2, 4.8, 5.4 / Platform 3.0, 3.6, 4.2, 4.8, 5.4

Nobel Biocare NobelActive / F-Series / Diameter 3.0, 3.5, 4.3, 5.0 / Platform 3.0, 3.5, 3.9 (4.3), 3.9 (5.0)

Neodent - Grand Morse / GM Series / Diameters 3.5, 3.75, 4.0, 4.3, 5.0, 6.0 / Platform 3.0

Biomet 3i - Certain / H-Series / Diameter 3.25, 4.0, 5.0 / Platform 3.4, 4.1, 5.0

Biomet 3i – External Hex / I-Series / Diameter 3.25, 3.75, 4.0, 5.0 / Platform 3.4, 4.1, 5.0

Nobel Biocare - Brånemark System / K-Series / Diameter 3.3, 3.75, 4.0, 5.0 / Platform 3.5, 4.1, 4.1, 5.1

Zimmer Dental Tapered Screw-vent / R-Series / Diameter 3.3, 3.7, 4.1, 4.7, 6.0 / Platform 3.5, 4.5, 5.7

Dentsply Implants - ASTRA TECH OsseoSpeed TX / S-Series / Diameter 3.5, 4.0, 4.5, 5.0 / Platform 3.5, 4.0, 4.5, 5.0

Dentsply Implants – XiVE S / T- Series / Diameter 3.4, 3.8, 4.5, 5.5 / Platform 3.4, 3.8, 4.5, 5.5

## 5.7 Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in Table 2. The Indications for Use Statement for the subject devices has been modified from the primary predicate (K190097) to include the implant-to-abutment compatibilities.

# K201711 – Traditional 510(k)

## CARES® Screw - Retained Bars and Bridges (SRBB)

510(k) Summary

The implant-to-abutment compatibilities (E-, EV-, F-, H-, I-, K-, R-, S-, and T-Series) are identical to the reference device, excluding the 3.0 mm implant diameter/3.0 mm platform diameter DENTSPLY Implants EV Series (K120414). Reverse Engineering Analysis for the addition of this new compatibility was conducted using OEM implant bodies, OEM abutments, and OEM abutment screws. Reverse engineering was not needed for the addition of the implant-to-abutment compatibilities for the GM-Series, because the implant-to-abutment connection dimensions were shared as part of a business partnership with the OEM company. The device materials of the subject device are identical to the reference device K170838.

Please note that the MRI compatibility reference device K180564 – MRI Safety Information Labeling Change is included for the MRI only. K150203 is included for reference to dynamic fatigue testing (this is the primary predicate to K170838).

The design step defined in the subject device allows to control the same design limits implemented in the primary predicate (K190097). The design of the CARES® Screw - Retained Bars and Bridges Framework is performed by a trained technician using a Commercial Off-The-Shelf (COTS) Software. The design parameters are identical between the subject devices and the primary predicate (K190097) and are respected during the design of the restoration. Once the design is finalized, the design file is digitally transferred to a Straumann milling center holding the appropriate Establishment Registration. The prosthetic restoration is then manufactured according 21 CFR 820 Quality System Regulations. After production, all CARES® Screw - Retained Bars and Bridges undergoes a rigid Quality Control. If the result is correct, production sends the device to the customer. The manufacturing process for the subject devices is identical to the primary predicate (K190097).

# K201711 – Traditional 510(k)

# CARES® Screw - Retained Bars and Bridges (SRBB)

510(k) Summary

| Feature | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| | *CARES® Screw - Retained Bars and Bridges* | *K190097 - Straumann CARES® Screw-Retained Bridges and Bars* | *K170838 – Medentika CAD/CAM TiBases* |
| **Indications for use** | CARES® Screw-retained Bridges and Bars are indicated for use as bars and bridges that attach to implants to provide support for prosthetic reconstructions such as bridges and overdentures. The final processed products have the purpose of restoring chewing function. CARES® Screw-retained Bridges and Bars are indicated for screw-retained restorations.<br><br>CARES® Screw - Retained Bars and Bridges are designed to interface with the following dental implant systems (Implant System Compatibility / Series / Implant diameter (mm) / Platform diameter (mm)):<br><br>Nobel Biocare Replace Select / E-Series / Diameters 3.5, 4.3, 5.0, 6.0 / Platform 3.5, 4.3, 5.0, 6.0<br>Dentsply Implants - ASTRA TECH OsseoSpeed EV / EV-Series / 3.0, 3.6, 4.2, 4.8, 5.4 / Platform 3.0, 3.6, 4.2, 4.8, 5.4<br>Nobel Biocare NobelActive / F-Series / Diameter 3.0, 3.5, 4.3, 5.0 / Platform 3.0, 3.5, 3.9 (4.3), 3.9 (5.0)<br>Neodent - Grand Morse / GM Series / Diameters 3.5, 3.75, 4.0, 4.3, 5.0, 6.0 / Platform 3.0<br>Biomet 3i - Certain / H-Series / Diameter 3.25, 4.0, 5.0 / Platform 3.4, 4.1, 5.0<br>Biomet 3i – External Hex / I-Series / Diameter 3.25, 3.75, 4.0, 5.0 / Platform 3.4, 4.1, 5.0<br>Nobel Biocare - Brånemark System / K-Series / Diameter 3.3, 3.75, 4.0, 5.0 / Platform 3.5, 4.1, 4.1, 5.1<br>Zimmer Dental Tapered Screw-vent / R-Series / Diameter 3.3, 3.7, 4.1, 4.7, 6.0 / Platform 3.5, 4.5, 5.7<br>Dentsply Implants - ASTRA TECH OsseoSpeed TX / S-Series / Diameter 3.5, 4.0, 4.5, 5.0 / Platform 3.5, 4.0, 4.5, 5.0<br>Dentsply Implants – XiVE S / T- Series / Diameter 3.4, 3.8, 4.5, 5.5 / Platform 3.4, 3.8, 4.5, 5.5 | Straumann® CARES® Screw-retained Bridges and Bars are indicated for use as bars and bridges that attach to implants to provide support for prosthetic reconstructions such as bridges and overdentures. The final processed products have the purpose of restoring chewing function. Straumann® CARES® Screw-retained Bridges and Bars are indicated for Screw-retained restorations. Straumann® CARES® Screw-retained Bridges and Bars are designed to interface with the Bone Level (BL), Tissue Level (TL), and BLX implants of the Straumann Dental Implant System (SDIS). | Medentika TiBase CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.<br><br>(Implant System Compatibility/ Series / Implant diameter (mm) / Platform Diameter (mm)):<br>Nobel Biocare Replace™ Select / E-Series / 3.5, 4.3, 5.0, 6.0 / 3.5, 4.3, 5.0, 6.0<br>Dentsply Implants/ASTRA TECH OsseoSpeed EV/ EV-Series / 3.6, 4.2, 4.8, 5.4 / 3.6, 4.2, 4.8, 5.4<br>Nobel Biocare NobelActive™ / F-Series / 3.5, 4.3, 5.0 / 3.5, 3.9 (4.3), 3.9 (5.0)<br>Biomet 3i Osseotite® Certain® / H-Series / 3.25, 4.0, 5.0 / 3.4, 4.1, 5.0<br>Biomet 3i Osseotite® / I-Series / 3.25, 3.75, 4.0, 5.0 / 3.4, 4.1, 5.0<br>Nobel Biocare Brånemark / K-Series / 3.3, 3.75, 4.0, 5.0 / 3.5, 4.1, 4.1, 5.1<br>Straumann Bone Level / L-Series / 3.3, 4.1, 4.8 / 3.3, 4.1, 4.8<br>Straumann Standard / N-Series / 3.3, 4.1, 4.8 / 3.5 (NNC), 4.8, 6.5<br>Zimmer Tapered Screw-Vent® / R-Series / 3.3, 3.7, 4.1, 4.7, 6.0 / 3.5, 4.5, 5.7<br>Astra Tech OsseoSpeed™ / S-Series / 3.5, 4.0, 4.5, 5.0 / 3.5, 4.0, 4.5, 5.0<br>Dentsply Friadent® Frialit/XiVE® / T-Series / 3.4, 3.8, 4.5, 5.5 / 3.4, 3.8, 4.5, 5.5<br>Dentsply Friadent® Ankylos® / Y-Series / 3.5, 4.5, 5.5, 7.0 / 3.5, 4.5, 5.5, 7.0<br><br>Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed copings and/or crowns are intended to be sent to Straumann for manufacture at a validated milling center. |

# K201711 – Traditional 510(k)

# CARES® Screw - Retained Bars and Bridges (SRBB)

510(k) Summary

| Feature | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| | *CARES® Screw - Retained Bars and Bridges* | *K190097 - Straumann CARES® Screw-Retained Bridges and Bars* | *K170838 – Medentika CAD/CAM TiBases* |
| **Material of the restoration** | Ti6Al4V, Titanium grade 5, conforming ASTM F 136 | Restorations:<br>Cobalt Chromium Alloy (CoCr)<br>Titanium Grade 4 | Ti6Al4V, Titanium grade 5, conforming ASTM F 136 |
| **Material of screws** | Ti6Al4V, Titanium grade 5, conforming ASTM F 136 | Screws:<br>Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb) | Ti6Al4V, Titanium grade 5, conforming ASTM F 136 |
| **Interface** | Non engaging | Non engaging | Engaging |
| **Restoration Types Supported** | Bridges from 2 units to 16 units (full-arch)<br>Bars from 2 units to 10 units | Bridges from 2 units to 16 units (full-arch)<br>Bars from 2 units to 10 units | Single restorations |
| **Design Workflow** | CAD- Commercial Off-The-Shelf (COTS) Software | CAD - CARES Visual Software | Straumann CARES System |
| **Manufacturing Workflow** | Straumann Milling Center | Straumann Milling Center | Straumann Milling Center |
| **Design Software** | Manual design by a trained dental technician under the Straumann Quality System using Commercial Off-The-Shelf (COTS) Software and based on defined design limit by work instruction and training | Straumann CARES Visual Software | Straumann CARES Visual Software |
| **Design Limits for Patient Specific Component** | Critical geometry parameters are controlled during CAD design step based on defined design limit by work instruction and training. After manufacturing the devices undergo rigid quality controls. | Critical geometry parameters are enforced by CARES Visual Software limits | Critical geometry parameters are enforced by CARES Visual Software limits |
| **Sterility** | Delivered non-sterile | Delivered non-sterile | Delivered non-sterile |
| **Sterilization by end user** | Yes | Yes | Yes |
| **Method of sterilization** | Moist heat (steam autoclave) | Moist heat (steam autoclave) | Moist heat (steam autoclave) |

| Feature | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| | *CARES® Screw - Retained Bars and Bridges* | *K190097 - Straumann CARES® Screw-Retained Bridges and Bars* | *K170838 – Medentika CAD/CAM TiBases* |
| **Mode of Action** | Screw-retained | Screw-retained | Screw-retained |
| **Reusable** | No | No | No |
| **Packaging** | Box package for the milled restoration and the screws | Box package for the restoration and the screws | The abutment in reclosable poly bag and the corresponding screws are individually packed in a plastic bag, co-packaged in a craft board box |

**Table 2 – Technological Characteristics**

## 5.8 Performance Testing

The implant to abutment connections for the E-, EV-, F-, H-, I-, K-, R-, S-, and T-Series are identical to the implant to abutment compatibilities of the reference devices (K170838), except for the addition of the 3.0 mm implant diameter/3.0 mm platform diameter DENTSPLY Implants EV Series (K120414), for which Reverse Engineering Analysis was conducted using OEM implant bodies, OEM abutments, and OEM abutment screws. For the addition of the new line of abutments (GM-Series), the implant to abutment connection dimensions were shared as part of a business partnership.

The change in design workflow from the CARES Visual Software to COTS software does not require additional testing to support substantial equivalence as the design parameters are identical between the subject devices and the primary predicate (K190097) and are respected during the design of the restoration by a trained dental technician under the Straumann Quality System to ensure the pre-defined design limits have been followed.

Dynamic fatigue testing was 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 that the CARES® Screw - Retained Bars and Bridges are equivalent to the predicate and reference devices.

The subject device materials and manufacturing process are identical to the primary predicate (K190097) and reference (K170838) devices, therefore, no new issues regarding biocompatibility were raised.

The sterilization process for the CARES® Screw - Retained Bars and Bridges, 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"*, and conforming to the ISO 17665-1 and ISO/TS 17665-2.

## 5.9 Conclusion

The documentation submitted in this premarket notification demonstrates the CARES® Screw - Retained Bars and Bridges are substantially equivalent to the primary predicate and reference devices.