June 26, 2019

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

Re: K190097
Trade/Device Name: Straumann® CARES® Screw-Retained Bridges and Bars
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 10, 2019
Received: April 11, 2019

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,

for Srinivas Nandkumar, Ph.D.
Acting 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)*
K190097

Device Name
Straumann® CARES® Screw-Retained Bridges and Bars

Indications for Use *(Describe)*

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).

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

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

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Andover, MA 01810

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Fax Number: +1 978 747 0023

Contact Person: Jennifer M. Jackson, MS

Director, Regulatory Affairs

Prepared By: Dr. Gordon Dodds

Manager Design Control QM, etkon GmbH

Date of Submission: June 14, 2019

5.2 Device

Trade Name: Straumann® CARES® Screw-Retained Bridges and Bars

Common Name: Endosseous dental implant abutment

Classification Name: Endosseous dental implant abutment

Regulation Number: 21 CFR 872.3630

Regulatory Class: II

Product Code: NHA

Classification Panel: Dental Devices

5.3 Predicate Device

Primary Predicate: K132844 – Straumann CARES Bone Level Screw-Retained Bars, Straumann CARES Bone Level Screw-Retained Bridges

Reference Devices: K173961 – Straumann BLX Implant System

K150203 – Medentika CAD/CAM Abutments

5.4 Device Description

The Straumann® CARES Screw-Retained Bridges and Bars ("SRBB") are used for the restoration of Straumann dental implants with different endosteal diameters, lengths and platforms (Figure 1). The purpose of this premarket notification is to expand the currently cleared abutment-to-implant interfaces to include the BLX implant system of the Straumann Dental Implant System (SDIS). The materials available include coron and titanium.

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 Straumann specifically for an individual patient.

SRBB devices are designed via Computer Aided Design (CAD). After importing a scan of the patient model, Straumann® CARES® Visual software includes the ability to generate digital restoration models incorporating the subject devices as well as the predicate devices. The digital restoration model is transferred to the milling center where the restoration is produced using Computer Aided Manufacturing (CAM)-techniques.

Figure 1 – Straumann® CARES® Screw-Retained Bridges and Bars

5.5 Indications for Use

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).

5.6 Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in Table 1. The change to the previously cleared primary predicate SRBBs is to add the BLX implant-to-abutment interface. No other technological changes (e.g., design parameters, process, materials, etc.) have been made as compared to the primary predicate other than the additional implant-to-abutment connection interface (BLX). The indications for use statement for the subject devices has been modified from the primary predicate to clarify the implant-to-abutment interfaces included. The reference devices (K173961) are included for comparison of the BLX interface. The reference devices (K150203) are included for comparison of the dynamic fatigue performance.

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICES	
	Straumann CARES® Screw-Retained Bridges and Bars	**K132844** **Straumann® CARES® Bone Level Screw-Retained Bars/Bridges**	**K173961** **Straumann BLX Implant System**	**K150203** **Medentika CAD/CAM Abutments**
Indications for Use	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).	Straumann CARES Screw-Retained Bridges and Bars are indicated for use as bars and bridges that attach to implants of the Straumann Dental Implant System (SDIS) to provide support for prosthetic reconstructions such as bridges and over-dentures. 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® Variobase® prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The prosthetic restoration (crowns) can be cemented onto the Straumann® Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they must be placed out of occlusion. 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.	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. Implant System Compatibility Series Implant Diameter (mm) Platform Diameter (mm) Nobel Biocare Replace™ Select E 3.5, 4.3, 5.0, 6.0 3.5, 4.3, 5.0, 6.0 Nobel Biocare NobelActive™ F 3.5, 4.3, 5.0 3.5, 3.9 (4.3), 3.9 (5.0) Biomet 3i Osseotite® Certain® H 3.25, 4.0, 5.0 3.4, 4.1, 5.0 Biomet 3i Osseotite® I 3.25, 3.75, 4.0, 5.0 3.4, 4.1, 5.0 Nobel Biocare Brånemark K 3.3, 3.75, 4.0, 5.0 3.5, 4.1, 4.1, 5.1 Straumann Bone Level L 3.3, 4.1, 4.8 3.3, 4.1, 4.8 Straumann Standard N 3.3, 4.1, 4.8 3.5(NNC), 4.8, 6.5 Zimmer Tapered Screw-vent® R 3.3, 3.7, 4.1, 4.7, 6.0 3.5, 4.5, 5.7 Astra Tech OsseoSpeed™ S 3.5, 4.0, 4.5, 5.0 3.5, 4.0, 4.5, 5.0 Dentsply Friadent® Frialit/XiVE® T 3.4, 3.8, 4.5, 5.5 3.4, 3.8, 4.5, 5.5 Dentsply Friadent® Ankylos® Y 3.5, 4.5, 5.5, 7.0 3.5, 4.5, 5.5, 7.0 Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.
Material	Restorations: Cobalt Chrome Alloy Titanium Grade 4 Screws: Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Restorations: Cobalt Chrome Alloy Titanium Grade 4 Screws: Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Vanadium alloy (Ti-6Al-4V)

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICES	
	Straumann CARES® Screw-Retained Bridges and Bars	**K132844 Straumann® CARES® Bone Level Screw-Retained Bars/Bridges**	**K173961 Straumann BLX Implant System**	**K150203 Medentika CAD/CAM Abutments**
Supported Straumann Interfaces	Bone Level – RC,NC Tissue Level – RN, WN BLX – RB, WB	Bone Level – RC,NC Tissue Level – RN, WN	BLX – RB, WB	Bone Level – RC,NC Tissue Level – RN, WN
SRBB Abutment Implant/ Apical Design	BL external cone TL internal cone BLX internal cone	BL external cone TL internal cone	Not applicable	Not applicable
Restoration Types Supported	Bridges and Bars from 2 units to full-arch	Bridges and Bars from 2 units to full-arch	Not applicable	Not applicable
Design Workflow	CAD	CAD	CAD	CAD
Manufacturing Workflow	Straumann Milling Center	Straumann Milling Center	Straumann Milling Center	Straumann Milling Center
Design Software	Straumann CARES Visual	Straumann CARES Visual	Straumann CARES Visual	Straumann CARES Visual
Design Limits for Bridges	Critical geometry parameters are enforced by CARES Visual limits	Critical geometry parameters are enforced by CARES Visual limits	Not applicable	Not applicable
Design Limits for Bars	Critical geometry parameters are enforced by CARES Visual limits	Critical geometry parameters are enforced by CARES Visual limits	Not applicable	Not applicable
Sterilization	Steam autoclave	Steam autoclave	Steam autoclave	Steam autoclave
Mode of Action	Screw-retained	Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained
Reusable	No	No	No	No

Table 1 – Comparison of technological features

5.7 Performance Data

Per *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments dated May 12, 2004*, the substantial equivalence of the subject device(s) are satisfactorily addressed via bench studies.

The following testing has been conducted:

- Dynamic fatigue testing conforming to FDA guidance (referenced above) and ISO 14801
  - The test environment was 0.9% NaCl at 37°
- Software validation conforming to the requirements of IEC 62304
- Sterilization validation conforming to ISO 17665-1 and ISO/TS 17665-2
- Biocompatibility testing according to ISO10993-1

5.8 Conclusion

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.