January 3, 2018

Institut Straumann AG
% Jennifer Jackson
Director, Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01801

Re: K172798
Trade/Device Name: Straumann® CARES® Abutments CoCr
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 4, 2017
Received: December 5, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 I. Steen -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*
K172798

Device Name

Straumann® CARES® Abutments CoCr

Indications for Use *(Describe)*

The Straumann® CARES® Abutments CoCr are indicated for single tooth replacement 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.

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

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1. 510(k) Summary — 510(k) Number: K172798

Submitter:	Straumann USA, LLC (on behalf of Institut Straumann AG) 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052
Contact Person:	Jennifer M. Jackson, MS Director of Regulatory Affairs and Quality +1 (978) 747-2509
Prepared By & Secondary Contact:	Shokoufeh Khodabandeh Regulatory Affairs and Compliance Manager Institut Straumann AG +41 61 965 1260
Date Prepared:	January 3, 2018
Product Code(s):	NHA
Device Class:	II
Classification Panel:	Dental
Classification Name:	Endosseous dental implant abutment (21 CFR 872.3630)
Common Name:	Endosseous dental implant abutment (21 CFR 872.3630)
Proprietary Name:	Straumann® CARES® Abutments CoCr
Predicate Device(s):	K150899 Straumann® CARES® Titanium Alloy (TAN) Abutments; Manufacturer Straumann
Reference Device(s):	K132844Straumann® CARES® SRBB; Manufacturer Straumann K101465 Straumann® CARES® Bridge, Straumann® CARES® Bar ; Manufacturer Straumann K083550 Modified S/SP/BL 3.3 Implants;Manufacturer Straumann K150203 Medentika CAD/CAM Abutments; Manufacturer Medentika Gmbh K162890 Small Diameter Implant (SDI); Manufacturer Straumann K062129 Straumann Dental Implant System: P.004 Implants; Manufacturer Straumann
Device Description:	Straumann® CARES® Abutments CoCr are used for the restoration of Straumann dental implant platforms RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit), and RC (Regular CrossFit). The Straumann® CARES® Abutments CoCr allow for individual customization regarding function and esthetics. Straumann® CARES® Abutments CoCr are designed by the dental laboratory technician either by means of a conventional wax-up model that is subsequently scanned or by scanning the intraoral situation and designing the shape by using a Straumann-approved software (such as Straumann® CARES® Visual). The design data is then transferred to a Straumann central milling center where the fabrication of the customized abutment is carried out. The Straumann® CARES® Abutments CoCr can be directly veneered.

Indications For Use:

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

Materials:

- Straumann CARES Abutments CoCr: cobalt-chromium based dental alloy, trade named coron. This material is identical to the coron material used in Straumann® CARES® SRBB (K132844 and K101465).
- Straumann Basal Screw: Titanium-6 aluminum-7 niobium alloy (Ti-6Al-7Nb, TAN). The basal screw component of the Straumann® CARES® Abutments CoCr are identical to the basal screw components of the Straumann predicates (K150899, K041295, K071357, and K062129).

Technological Characteristics:

A comparison of the relevant technological characteristics between the subject and the primary predicate is provided in the table that follows.

Feature	**Subject Device** Straumann® CARES® Abutments CoCr	**Primary Predicate Devices** Straumann® CARES® Titanium Alloy (TAN) Abutments **(**K150899**)**	**Equivalence Discussion**
Indication for use	The Straumann® CARES® Abutments CoCr are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained.	The Straumann® CARES® Abutments TAN are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained.	Identical
Compatible Implants	Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the RN and WN implant-to-abutment interface geometries.	Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the NN, RN, WN implant-to-abutment interface geometries.	Identical
Material	CARES abutment: Cobalt-chromium Alloy (coron) Basal screw: Titanium alloy (Ti6Al7Nb), TAN	CARES abutment: Titanium alloy (Ti6Al7Nb), TAN Basal screw: Titanium alloy (Ti6Al7Nb), TAN	Equivalent

<table>
<tr><th>Feature</th><th>Subject Device
Straumann® CARES® Abutments CoCr</th><th>Primary Predicate Devices
Straumann® CARES® Titanium Alloy (TAN) Abutments
(K150899)</th><th>Equivalence Discussion</th></tr>
<tr><td>Design Limits:</td><td>Max. Angulation 30°
Minimum thickness 0.33 mm
<table><tr><th>Tooth Position</th><th>Minimum surface area mm²</th></tr><tr><td>7,10, 24,25</td><td>37</td></tr><tr><td>4,5,12,1320,21, 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></table></td><td>Max. Angulation 30°
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<tr><td>Construction</td><td>One-piece solid Abutment supplied with the compatible basal screw</td><td>One-piece solid abutment supplied with the compatible basal screw</td><td>Identical</td></tr>
<tr><td>Packaging</td><td>The abutment in reclosable poly bag and the corresponding basal screw is individually packed in a blister, co-packaged in a craft board box</td><td>The abutment in reclosable poly bag and the corresponding basal screw is individually packed in a blister, co-packaged in a craft board box.</td><td>Identical</td></tr>
<tr><td>Sterility</td><td>Provided non-sterile.
To be sterilized by the user in a steam autoclave process.</td><td>Provided non-sterile.
To be sterilized by the user in a steam autoclave process.</td><td>Identical</td></tr>
<tr><td>Fatigue performance</td><td>Tested according to ISO 14801</td><td>Tested according to ISO 14801</td><td>Equivalent</td></tr>
</table>

Performance Data: The material used in the manufacture of Straumann® CARES® Abutments CoCr is a cobalt-chromium alloy which meets the requirements of ISO 22674 type 4. Bench testing was performed to evaluate the performance of the proposed Straumann® CARES® Abutments CoCr. Dynamic fatigue tests were conducted according to the ISO 14801 "*Dentistry - Implants - Dynamic fatigue test for endosseous dental implants*" and FDA guidance document *"Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments"*. The biocompatibility of the subject device is demonstrated by "Biological evaluation of

medical devices – Part 1: Evaluation and testing within a risk management process", ISO 10993-5:2009 "Tests for in vitro cytotoxicity", and ISO 10993-18 "Chemical characterization of materials". Veneering performance testing of the Straumann CoCr alloy (coron) has been performed per ISO 9693-1, Dentistry – Compatibility testing – Part 1: Metal ceramic systems; A final workflow validation according to internal procedures has also been conducted. Corrosion resistance was demonstrated according to ISO 10271:2011 – "Corrosion test methods for metallic materials". Sterilization validation was carried out via the overkill method, 1/2 cycle, to a Sterilization Assurance Level (SAL) of 10^{-6} in accordance to the ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO 17665-2.

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.