August 19, 2020

Straumann USA, LLC (On behalf of Institut Straumann AG)
Chanrasmey White
Regulatory Affairs Specialist
60 Minuteman Road
Andover, Massachusetts 01810

Re: K200597
Trade/Device Name: Straumann® BLX Gold Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 16, 2020
Received: July 20, 2020

Dear Chanrasmey White:

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.
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)*
K200597

Device Name
Straumann® BLX Gold Abutments

Indications for Use *(Describe)*

Straumann abutments are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns, bridges, and overdentures.

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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5 510(k) Summary

5.1 Submitter

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

60 Minuteman Road

Andover, MA 01810

Phone Number: 978-747-2614

Fax Number: 978-747-0023

Contact Person: Chanrasmey White

Date of Submission: August 18, 2020

5.2 Device

Trade Name: Straumann® BLX Gold Abutments

Common Name: Endosseous Dental Implant Abutments

Classification Name: Endosseous Dental Implant Abutments

Regulatory Class: II (21 CFR 872.3630)

Product Code: NHA (21 CFR 872.3630)

5.3 Predicate Device

Primary Predicate:

K070549 – RC Gold Abutments

Reference Predicate:

K072497 – NC Gold Abutment, crowns

K071888 – Gold Abutment for Bridge

K190662 – MRI Compatibility for Existing Straumann Dental Implant System

K173961 – BLX Implant System

5.4 Device Description

The Straumann prosthetic line consist of abutments which are used for the restoration of Straumann dental implants of different types, endosteal diameters, lengths and platforms. They are available in a variety of shapes and sizes to fit individual patient needs.

The Straumann BLX Gold Abutments consist of a Ceramicor® alloy base, which is fixed to the implant by mean of a basal screw made of Ti-6Al-7Nb, Titanium Aluminum Niobium (TAN). The screw channel is protected during the lab procedure with a modeling aid made of Polyoxymethylene (POM) which is friction fit to the Ceramicor® alloy base. The modeling aid is a burn-out sleeve for casting and the combination of base and modeling aid is designed to be used together with Straumann BLX Implants having the TorcFit™, conical connection.

5.5 Indications for Use

Straumann abutments are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns, bridges, and overdentures.

5.6 Technological Characteristics

The subject device is equivalent to the primary predicate cleared per K070549 and reference devices cleared per K072497 and K071888 with the exception of the implant to abutment connection which is TorcFit™ to fit the implants of the BLX Implant System cleared per K173961. The reference device K190662 is included to address MRI compatibility only.

The technological characteristics of the proposed BLX Gold Abutments are compared to the primary predicate in Table 1.

K200597 Traditional 510(k)

Straumann® BLX Gold Abutments

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
K Number	**K200597**	**K070549**	**K072497**	**K071888**
Indications for Use	Straumann abutments are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns, bridges, and overdentures.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.
Material	Ceramicor®	Ceramicor®	Ceramicor®	Ceramicor®
Abutment Shape in Coronal Portion	Axial screw access hole for placement of abutment into implant	Axial screw access hole for placement of abutment into implant	Axial screw access hole for placement of abutment into implant	Axial screw access hole for placement of abutment into implant
Design of Basal Portion of Abutment	TorcFit™ Connection for BLX Implants (conical connection)	CrossFit® Connection for BL/BLT Implants (conical connection)	CrossFit® Connection for BL/BLT Implants (conical connection)	CrossFit® Connection for BL/BLT Implants (conical connection)
Restoration	Crown and Bridge	Crown	Crown	Bridge
Diameter	3.8 mm, 4.5 mm, and 5.5 mm	4.5 mm	3.8 mm	4.7 mm
Gingiva Height	1.5 mm	3.7, 3.8, 5.2 mm	3.7 mm	5.2 mm
Total Abutment Height	4.5 mm, 6.8 mm	8.2 mm	6.5 mm	6.2 mm
Prosthesis Type	Cemented or screw retained	Cemented or screw-retained	Cemented or screw-retained	Cemented or screw-retained
Base Screw	Ti-6Al-7Nb Basal Screw	Ti-6Al-7Nb Basal Screw	Ti-6Al-7Nb Basal Screw	Ti-6Al-7Nb Basal Screw
Maximum Angulation	30°	30°	30°	30°

Table 1 – Comparison Matrix

5.7 Performance Data

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

Biocompatibility Testing

The subject devices have been assessed for biological safety according to ISO 10993-1:2009 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” and to the FDA Guidance document “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’, Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016” for the subject device.

The subject device is made out of the same material as the primary predicate device, therefore, biocompatibility is represented by the primary predicate. The subject devices are equivalent with regard to nature of body contact, contact duration, material formulation and sterilization methods compared to the primary and reference predicate devices and therefore, no new testing has been performed.

Sterilization

The proposed BLX Gold Abutments are single patient devices and are provided non-sterile. The recommended end user sterilization via Moist Heat Steam sterilization has been validated according to ISO 17665-1 and ISO 17665-2 and to applicable recommendations in the FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff, Document issued on: March 17, 2015”.

Bench Testing

Dynamic fatigue, static strength, and loosening 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.” Testing was performed on worst-case construct. The worst-case construct is based on several device features such as diameter, wall thickness and orientation and intends to represent the performance behavior of all the devices within

this submission. The worst-case construct was tested and results demonstrated equivalence to the predicate devices.

5.8 Conclusion

The documentation submitted in this premarket notification demonstrates the subject devices are substantially equivalent to the predicate devices.