Straumann USA, LLC (on behalf of Institut Straumann AG)
% Jennifer Jackson
Director, Regulatory Affairs & Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

November 14, 2017

Re: K171769
Trade/Device Name: Straumann® PURE Ceramic Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: August 15, 2017
Received: August 16, 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,

Mary S. Runner -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)*
K171769

Device Name
Straumann® PURE Ceramic Implants

Indications for Use *(Describe)*
The Straumann® PURE Ceramic Implant (Monotype) is indicated for restoration in single tooth gaps and in an edentulous or partially edentulous jaw. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components.
The ø3.3 mm reduced diameter implants are recommended for central and lateral incisors only.

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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510(k) Summary

5.1 Submitter

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

60 Minuteman Road Andover, MA 01810

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Contact Person: Jennifer M. Jackson, MS

Prepared By: Chanrasmey White

Date of Submission: November 14, 2017

5.2 Device

Trade Name: Straumann® PURE Ceramic Implants

Common Name: Endosseous Dental Implant

Classification Name: Implant, Endosseous, Root-Form

Regulatory Number: §872.3640

Classification: Class II

Product Code: DZE

Subsequent Product Code: NHA

5.3 Predicate Device

Primary Predicate: K151328, Straumann® PURE Ceramic Implants

5.4 Device Description

The Straumann® PURE Ceramic Implants are made of 100% yttrium-stabilized zirconia. The endosteal region presents macro- and micro-roughness, a ZLA surface. The implant has a 1.8 mm high machined neck. The implant features a monotype design where the ceramic abutment for final restoration is already built in. Straumann® PURE Ceramic Implant prosthetic components are identified with RD (Regular Diameter)

corresponding to the neck diameter of 4.8 mm, and ND (Narrow Diameter) corresponding to the neck diameter of 3.5 mm.

5.5 Indications for Use

The Straumann® PURE Ceramic Implant (Monotype) is indicated for restoration in single tooth gaps and in an edentulous or partially edentulous jaw. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components.

The ø3.3 mm reduced diameter implants are recommended for central and lateral incisors only.

5.6 Technological Characteristics

The proposed Straumann® Pure Ceramic Implants intended use, material, fundamental operating principles and overall design are identical to the primary predicate device, K151328. The subject device is identical to the primary predicate, K151328 with the exception that the subject device will be delivered to the user sterile via Ethylene Oxide as opposed to sterile via H_2O_2 plasma.

The additional components mentioned in the predicate device indications for use statement are not subject to this submission as the change only impacts the sterilization of the endosseous dental implants. The technological characteristics of the subject devices are compared to the predicate device in the following table.

Straumann® PURE Ceramic Implants

510(k) Summary

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
K Number	**K171769**	**K151328**
Indications for Use	The Straumann® PURE Ceramic Implant (Monotype) is indicated for restoration in single tooth gaps and in an edentulous or partially edentulous jaw. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. The ø3.3 mm reduced diameter implants are recommended for central and lateral incisors only.	The Straumann® PURE Ceramic Implant (Monotype) is indicated for restoration in single tooth gaps and in an edentulous or partially edentulous jaw. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. The ø3.3 mm reduced diameter implants are recommended for central and lateral incisors only. The Straumann® PURE Ceramic Implant Protective Cap is intended to protect the Straumann® PURE Ceramic Implant (Monotype) during the healing phase after implant placement for up to 6 months. Temporary copings are intended to serve as a base for temporary crown or bridge restoration for the Straumann® PURE Ceramic Implant (Monotype) for up to 30 days.
Material	Y-TZP	Y-TZP
Surface Treatment	Sand-blasted, large-grit, acid etched	Sand-blasted, large-grit, acid etched (ZLA®)
Apical Diameter	Ø3.3 and Ø4.1 mm	Ø3.3 and Ø4.1 mm
Coronal Diameter	Ø3.5 and Ø4.8 mm	Ø3.5 and Ø4.8 mm
Length	8, 10, 12, and 14 mm	8, 10, 12, and 14 mm
Implant Design	Cylindrical Monotype	Cylindrical Monotype
Implant Neck	1.8 mm, machined	1.8 mm, machined
Thread Pitch	0.8 mm	0.8 mm
Implant/Abutment Connection	None (Monotype)	None (Monotype)
Sterilization	End user receives product sterilized per Ethylene Oxide Validated per ISO 11135 to a SAL of 10^{-6}	End user receives product sterilized per H_2O_2 – plasma in accordance with DIN EN 556-1:2002 (equivalent to ANSI AAMI ST67:2011) to a SAL of 10^{-6}

Table 1: Technological Characteristics Subject Device compared to Primary Predicate

5.7 Performance Data

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

Sterilization and Shelf-Life

A sterilization validation was performed per ISO 11135, *Sterilization of healthcare products – Ethylene Oxide – Requirements for development, validation and routine control of a sterilization process for medical devices*, using the Half Cycle Overkill Approach. The validation demonstrates that the sterilization process and equipment is capable of reliably and consistently sterilizing the subject device to a minimum Sterility Assurance Level (SAL) of 10^{-6}.

A transportation study has been performed per ISTA 2A to demonstrate the integrity of the sterile barrier system considering the new sterilization process. The subject devices continue to meet product release requirements after being subjected to worst-case environmental and handling changes.

A packaging stability study was performed to demonstrate the integrity of the packaging system and the sterile barrier system after sterilization process via Ethylene Oxide, handling, distribution, transport and storage up to the defined product shelf life. The subject devices continue to meet product release requirements after being subjected to worst-case environmental and handling changes.

Shelf-Life studies have been conducted in accordance with ASTM F1980.

Biocompatibility Testing

The biological safety of the Straumann® PURE Ceramic Implants sterilized via Ethylene Oxide was re-evaluated and further biocompatibility testing was required according to ISO and FDA standard (FDA, 2016; ISO 10993-1, 2009). EO and ECH residues were not detected in the chemical analysis and no cytotoxicity was observed. Based on the test results the change in sterilization method did not affect the biological safety profile of the devices.

Bench Testing

Mechanical testing (static, dynamic fatigue and torque) and surface chemistry analysis was performed to demonstrate the new sterilization method does not affect product performance. Static and dynamic fatigue strength testing was performed per ISO 14801:2007 and the FDA-Guidance to *"Root-form endosseous dental implants*

and endosseous dental implant abutments." All mechanical testing performed demonstrated the new sterilization method does not affect the product performance after being subjected to hydrothermal aging. Cleanliness analysis demonstrated no significant difference in surface chemistry between H_2O_2 plasma (sterility method per predicate device) and EO sterilization.

5.8 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® PURE Ceramic Implants are substantially equivalent to the predicate device and do not pose new issues of safety and effectiveness.