Institut Straumann AG
% Jennifer Jackson
Sr. Director Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Rd.
Andover, Massachusetts 01810

December 10, 2024

Re: K241391
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: May 15, 2024
Received: November 15, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241391

Device Name
Straumann® PURE Ceramic Implants

Indications for Use *(Describe)*
The Straumann® PURE Ceramic Implant 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)*

[X] 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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Traditional 510(k) Submission

Straumann® PURE Ceramic Implants

K241391 510(k) Summary

510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: Institut Straumann AG Peter Merian weg 12 4052 Basel, Switzerland
Contact Person:	Jennifer M. Jackson, MS Sr.Director of Regulatory Affairs & Quality Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Prepared By:	Corinne Arimatea RA & Compliance Manager Institut Straumann AG Phone number: +41619651217
Date Prepared:	December 09, 2024

Name of the Device

Trade Names:	Straumann® PURE Ceramic Implants
Common Name:	Endosseous dental implant
Classification Name:	Endosseous dental implant
Regulation Number:	21 CFR 872.3640
Device Classification:	II
Product Code(s):	Primary product code - DZE

Predicate Device(s)

Primary Predicates:

- *K171769 - Straumann® PURE Ceramic Implants*

Reference Devices:

- *K180477 - Straumann® PURE Ceramic Implants*
- *K210336 - Neodent Implant System – Zirconia Implant System*
- *K201491 - Neodent Implant System – Zirconia Implant System*

Device Description

The Straumann® PURE Ceramic Implants (Tissue Level Monotype and Tissue Level two-piece design) are part of the Straumann® Dental Implant System, which is an integrated system of endosseous dental implants with corresponding instruments and prosthetic parts. The Straumann® PURE Ceramic Implants are solid screw implants with a bone anchorage surface that is large-grit sandblasted and acid-etched (ZLA® surface). The implants have a 1.8 mm high machined transmucosal neck. The Straumann® PURE Ceramic Implant has a two -piece design with internal connection based on features of the Straumann® Tissue Level Standard Plus and Straumann® Bone Level Implants. The Straumann® PURE Ceramic Implant Monotype features a monotype design where the ceramic abutment for final restoration is already built in.

Indications for Use

The Straumann® PURE Ceramic Implant 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.

Technological Characteristics

The indications for use and technological characteristics of the subject devices are consistent with those of the primary predicate and reference devices as detailed in the following table.

Table 1. Comparative Summary of the Indications for Use and Technological Characteristics.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE	REFERENCE DEVICES			EQUIVALENCE DISCUSSION
K Number/ name	**K241391 Straumann® PURE Ceramic Implants**	**K171769 Straumann® PURE Ceramic Implants**	**K180477 Straumann PURE Ceramic Implant System**	**K210336 Neodent Implant System - Zirconia Implant System**	**K201491 Neodent Implant System - Zirconia Implant System**	
Indications for Use	The Straumann® PURE Ceramic Implant 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 is indicated for the restoration of single-tooth gaps and in edentulous or partially edentulous jaws. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components.			Similar to the primary predicate, the word monotype was removed since the subject devices encompass monotype and two-piece devices.
Material	Yttrium-stabilized zirconium dioxide (Y-TZP)	Yttrium-stabilized zirconium dioxide (Y-TZP)	Yttrium-stabilized zirconium dioxide (Y-TZP)	Yttrium-stabilized zirconium dioxide (Y-TZP)	Yttrium-stabilized zirconium dioxide (Y-TZP)	Identical to primary predicate
Surface Treatment	Sand-blasted, large-grit, acid etched (ZLA®)	Sand-blasted, large-grit, acid etched (ZLA®)	Sand-blasted, large-grit, acid etched (ZLA®)	Sand-blasted, acid etched	Sand-blasted, acid etched	Identical to primary predicate

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE	REFERENCE DEVICES			EQUIVALENCE DISCUSSION
K Number/ name	**K241391 Straumann® PURE Ceramic Implants**	**K171769 Straumann® PURE Ceramic Implants**	**K180477 Straumann PURE Ceramic Implant System**	**K210336 Neodent Implant System - Zirconia Implant System**	**K201491 Neodent Implant System - Zirconia Implant System**	
Implant Diameter	Ø3.3 and Ø4.1 mm	Ø3.3 and Ø4.1 mm	Ø4.1 mm	Ø3.75 mm	Ø4.3 mm	Identical to reference devices K180477 and K171769.
Implant Length	8, 10, 12 and 14 mm	8, 10, 12 and 14 mm	8, 10, 12 and 14 mm	10, 11.5 and 13 mm	8, 10, 11.5 and 13 mm	Identical to reference devices K180477 and K171769.
Implant Design	Straight cylindrical implant body & Cylindrical Monotype	Cylindrical Monotype	Straight cylindrical implant body	Apically Tapered format Trapezoidal threads profile	Apically Tapered format Trapezoidal threads profile	Identical to reference devices K180477 and K171769.
Thread Pitch	0.8 mm	0.8 mm	0.8 mm	n/a	n/a	Identical to reference devices K180477 and K171769.
Sterilization Method	Ethylene Oxide	Ethylene Oxide (K171769) Plasma (K151328)	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Identical to reference devices K180477 and K171769.

Materials

The purpose of this submission is to support a change in the raw material supplier. The Straumann® PURE Ceramic Implants are made of Yttrium-stabilized zirconium dioxide (Y-TZP).

Summary of Nonclinical Testing

Nonclinical testing data submitted or referenced to demonstrate substantial equivalence in this 510(k) includes:

- 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 ISO 14801 "Dentistry — Implants — Dynamic loading test for endosseous dental implants" and demonstrated the subject devices are equivalent to the primary predicate and reference devices. The test was conducted in saline (2 Hz and 37°C) at 2 million cycles.
- Biological assessment was performed according to ISO 10993-1 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, (September 8, 2023). Cytotoxicity and chemical extraction tests were performed. No leachable substances were released in cytotoxic concentrations from the test item.
- K180477 & K171769 (Institut Straumann AG) referenced for sterilization validation in accordance with ISO 11135, "Sterilization of health care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices," using the Half Cycle approach of the Overkill method. The subject devices are not represented to be "non-pyrogenic".
- K180477 & K171769 (Institut Straumann AG) referenced for the packaging stability study and shelf-life study in accordance with ASTM F1980.
- The Straumann PURE Ceramic implants are non-magnetic and do not include an electrical component. As such, the subject devices are not acted upon by the application of

magnetic fields typical of Magnetic Resonance Imaging equipment. Therefore, the Straumann PURE Ceramic Implants do not raise concerns regarding electromagnetic compatibility and electrical safety, as the reference devices K180477 and K171769. However, the prosthetic components could be manufactured from metal material that can be affected by MRI environment. The MRI compatibility status must consider the clinically relevant construction, which may include assembly with metal devices that can be affected by MRI such as abutments and screws. Therefore, all devices are deemed to be MR Conditional.

- The ZLA® surface features a topography characterized by macro- and micro-roughness of the subject devices and is identical to the reference devices cleared under K180477 and K171769.

Conclusion

The data included in this submission demonstrate substantial equivalence to the predicate device listed above. Performance testing and comparison to previous clearances show that the subject devices are substantially equivalent.