February 8, 2021

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

Re: K202942
Trade/Device Name: Straumann® 4 mm Short Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: November 9, 2020
Received: November 10, 2020

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,

Andrew Steen
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)*

K202942

Device Name

Straumann® 4 mm Short Implants

Indications for Use *(Describe)*

Straumann® 4 mm Short Implants are indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone and with adequate bone quality that allows primary stability after implant insertion, where a longer implant cannot be placed due to limited vertical bone height. The recommended healing time before loading is between 10 to 12 weeks.

The 4 mm Short Implants are specifically recommended for:

- Fixed partial dentures/splinted units (one implant per unit)
- Pontic cases in combination with at least one longer implant
- Fully edentulous cases with at least one 4 mm Short Implant in combination with 2 longer implants in the anterior region and at least four total implants

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.

5 510(k) Summary

5.1 Submitter's Contact Information

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 Phone Number: +1 978 747-2509 Fax Number: +1 978 747-0023
Prepared By & Alternate Contact:	Chanrasmey White, MS Regulatory Affairs Specialist Straumann, USA, LLC Phone Number: +1 978 747-2516 Fax Number: +1 978 747-0023
Date of Submission:	February 8, 2021

5.2 Name of the Device

Trade Names:	Straumann® 4 mm Short Implants
Common Name:	Endosseous Dental Implant
Classification Name:	Endosseous Dental Implant
Regulation Number:	§872.3640
Device Classification:	II
Product Code(s):	DZE
Classification Panel:	Dental

5.3 Predicate Device(s)

Primary Predicate:

- K130222, Straumann Dental Implant System

Reference Devices:

- K092035, Bicon Implants with a 2.5 mm Internal Connection
- K123022, Neodent Implant System
- K190662, MRI Compatibility for Existing Straumann Dental Implant Systems

5.4 Device Description

The Straumann® Dental Implant System is an integrated system of endosseous dental implants with corresponding abutments, healing abutments, closure screws and surgical and prosthetic parts and instruments. Straumann® Roxolid® dental implants are solid screw implants comprised of a titanium-zirconium alloy with the hydrophilic SLActive® bone anchorage surface that is large-grit sandblasted and acid-etched. In addition, SLActive® is in a chemically activated state, which is preserved by storage in a NaCl solution.

This premarket notification serves to add new dental implants to the Straumann Dental Implant System portfolio that are 4 mm in length. Other than the implant length, the subject devices are physically identical to the primary predicate tissue level devices except for the implant thread which is identical to the bone level primary predicate devices cleared under K130222.

The Straumann® 4 mm Short Implants are manufactured from the Roxolid® material with the SLActive® surface and are available in Ø4.1 mm with a Regular Neck (RN) Tissue Level implant/abutment interface and in Ø4.8 mm with an RN or Wide Neck (WN) Tissue Level implant/abutment interface.

5.5 Intended Use

Straumann® 4 mm Short Implants are intended for oral endosteal implantation in the jaw and for the functional oral rehabilitation of edentulous and partially edentulous patients.

5.6 Indications for Use

Straumann® 4 mm Short Implants are indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone and with adequate bone quality that allows primary stability after implant insertion, where a longer implant cannot be placed due to limited vertical bone height. The recommended healing time before loading is between 10 to 12 weeks.

The 4 mm Short Implants are specifically recommended for:

- Fixed partial dentures/splinted units (one implant per unit)
- Pontic cases in combination with at least one longer implant
- Fully edentulous cases with at least one 4 mm Short Implant in combination with 2 longer implants in the anterior region and at least four total implants

5.7 Technological Characteristics

There are no changes to the materials, surface treatments, fundamental operating principles, or sterilization processes or procedures as a result of the proposed changes. The subject devices have a new implant length of 4 mm. The technological characteristics of the subject device are compared to the primary predicate and reference devices in Table 1.

Table 1 addresses the similarities and differences between the subject and predicate device. The subject device has more restrictive Indications for Use compared to the primary predicate. The differences in the Indications for Use are to address the short length of the implant and are narrower than the primary predicate device. Performance testing and clinical data provided demonstrates equivalency in product performance.

No new surgical instruments are being introduced. No new secondary components (i.e., abutments, closure screws, etc.) are being introduced as the currently cleared portfolio is compatible with the subject devices.

The reference device K190662 is included for reference to the MRI compatibility.

K202942 – Traditional 510(k)

Straumann® 4 mm Short Implants

510(k) Summary

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	**Straumann® 4 mm Short Implants (K202942)**	**Straumann® Dental Implant System (K130222)**	**Neodent Implant System (K123022)**	**Bicon Implants with 2.5 mm Internal Connection (K092035)**
Indications for Use	Straumann® 4 mm Short Implants are indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone and with adequate bone quality that allows primary stability after implant insertion, where a longer implant cannot be placed due to limited vertical bone height. The recommended healing time before loading is between 10 to 12 weeks. The 4 mm Short Implants are specifically recommended for: • Fixed partial dentures/splinted units (one implant per unit) • Pontic cases in combination with at least one longer implant • Fully edentulous cases with at least one 4 mm Short Implant in combination with 2 longer implants in the anterior region and at least four total implants	Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding components (abutments).	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Titamax WS implant is indicated for a delayed loading protocol. The Facility implant is indicated for replacement of maxillary lateral incisors, mandibular incisors or retention of overdentures.	The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.
Material	Roxolid® (Ti-Zr alloy)	Roxolid® (Ti-Zr alloy)	Commercially pure titanium, Grade 4	Surgical grade titanium alloy (Ti-6Al-4V)
Surface Treatment	SLActive®	SLActive®	Grit blasted, acid etched	Grit blasted, acid etched, and hydroxylapatite

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	**Straumann® 4 mm Short Implants (K202942)**	**Straumann® Dental Implant System (K130222)**	**Neodent Implant System (K123022)**	**Bicon Implants with 2.5 mm Internal Connection (K092035)**
Apical Diameter	Ø4.1 and Ø4.8 mm	Ø4.1 and Ø4.8 mm	Ø3.3, Ø4.3, and Ø5.3 mm	Ø4.0
Coronal Diameter	Ø4.8 and Ø6.5 mm	Ø4.8 and Ø6.5 mm (TL) Ø4.1 and Ø4.8 mm (BL)	Ø4.0, Ø5.0, and Ø6.0 mm	Unknown
Length	4 mm	6, 8, 10, 12, 14, and 16 mm (TL) 8, 10, 12, and 14 mm (BL)	5 and 6 mm	5 mm
Implant Design	Cylindrical	Cylindrical	Cylindrical	Cylindrical
Implant Neck Height	1.8 mm, smooth machined	1.8 mm, smooth machined (TL) None (BL)	None	None
Thread Pitch	0.8 mm	1.25 mm (TL) 0.8 mm (BL)	0.6 mm (Ø4.0) 0.8 mm (Ø5.0 and Ø6.0)	Unknown
Implant/ Abutment Connection	8° cone, internal octagon, 45° shoulder	8° cone, internal octagon, 45° shoulder (TL) 15° cone, 4 grooves/protrusions (BL)	Morse taper	Locking Taper
Compatible Abutments	Straight Abutments	Straight and angled abutments	Straight abutments	Straight and angled abutments
Healing Protocol	10-12 weeks	3-4 weeks	No immediate loading	10-12 weeks

Table 1 – Comparison Matrix

5.8 Performance Testing

The following performance data support the substantial equivalence determination.

5.8.1 Sterilization Validation and Shelf Life

The implants will be provided sterile via gamma irradiation at a dose of 25 kilogray (2.5 Mrad) minimum and will be sterilized after packaging. A sterility assurance level (SAL) of 10^{-6} had been validated in accordance with ISO 11137-1:2006, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, 2006-04-05*. The validation method used was the over kill bioburden method in accordance with ISO 11137-2:2006, *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*.

The packaging of the subject devices is identical to the packaging of the primary predicate device and the shelf life is 5 years when considering that the materials are not adversely affected by time.

There are no changes to the sterilization method or processes when compared to the Straumann predicate devices.

Pyrogenicity information provided is based on FDA Guidance on "*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile*, issued on 21 January 2016." The subject devices will not be labeled as non-pyrogenic. The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on a blood contacting and implanted device.

5.8.2 Biocompatibility Testing

Biological assessment has been performed 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 each of the subject devices.

The subject devices have the identical nature of body contact, contact duration, material formulation and sterilization methods compared to the primary predicate devices.

5.8.3 Performance Testing – Bench

Evaluation of the endosseous surface area was conducted for the subject devices as well as the primary predicate and reference devices. The surface areas were evaluated for the total endosseous surface, initial bone-to-implant contact, as well as with simulated 1 and 2 mm of bone loss.

Dynamic fatigue 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" and a modified ISO 14801 (Dentistry – Implants – Dynamic fatigue test for endosseous dental implants) test set-up due to the length of the subject devices. The test environment for the subject devices was ambient air. The Straumann® 4 mm Short Implants met the defined acceptance criteria and the mechanical strength requirements for its intended use. The results of the dynamic fatigue testing demonstrated the subject devices are equivalent to the primary predicate devices.

5.8.4 Performance Testing – Clinical

A review and summary of published clinical literature evaluating the use of 4 mm short implants in fully and partially edentulous adult patients and a summary of the complaint trends and vigilance reporting associated with the use of Straumann 4 mm short dental implants has been submitted to support substantial equivalence. Parameters evaluated in the clinical literature provided included study name, number of study participants, number of implants placed, duration of follow-up (in years); implant placement site, implant failures, survival rates and alveolar bone loss.

The clinical literature represents 57 cases with 118 implants of 4.1 mm diameter x 4 mm length, with 12 to 27 months of follow-up. Clinical cases in the literature were represented by the following patient scenarios:

- Fixed partial dentures/splinted units (one implant per unit)
- Pontic cases in combination with at least one longer implant
- Fully edentulous cases with at least one 4 mm Short Implant in combination with 2 longer implants in the anterior region and at least four total implants
- Delayed loading

Survival rates were at least 90%, with most failures attributed to early loss. This is comparable with data from 6 mm implants, in which the mean failure rate was 93.7%, also with most failures attributed to early loss. The available data indicates the subject dental implants may be used reliably and predictably with comparable survival and success rates to the primary predicate devices.

Post-market assessment via complaint trends and vigilance reporting data reflected 42,760 sales of 4.1 mm diameter x 4 mm length implants and 12,119 sales of 4.8 mm diameter x 4 mm length implants from September 2013 to September 2020. The overall complaint rate was 4.20% to 4.47%, with 3.41% to 3.84% of cases due to early loss. This is comparable with data from the primary predicate (implants with the same diameters but with 6 mm length), in which the overall complaint rate ranged from 3.00% to 4.07%, with early loss accounting for 2.27% to 2.57% of cases.

The results being presented in this premarket notification meet the definition of valid scientific data as defined in 21 CFR 860.7. The results are being presented in accordance with the guidance document "*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Abutments*".

The clinical data suggest performance of the Straumann® 4 mm Short Implants is equivalent to the primary predicate device if used according to the indications for use.

5.9 Conclusion

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