December 9, 2019

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

Re: K191895
Trade/Device Name: Straumann® Mini Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: September 9, 2019
Received: September 10, 2019

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,

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)*

K191895

Device Name :

Straumann® Mini Implants

Indications for Use *(Describe)*

Straumann® Mini Implants ∅2.4 mm are suitable for oral endosteal implantation in the upper and lower jaw of fully or partially edentulous patients. The implants can be placed with immediate function when good primary stability is achieved. Straumann® Mini Implants are intended for the stabilization of removable dentures.

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'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 E-mail: jennifer.jackson@straumann.com
Prepared By & Alternate Contact:	Viviana Horhoiu Regulatory Affairs and Compliance Manager Institut Straumann AG Phone number : +41 61 965 1512
Date of Submission:	December 9, 2019

5.2 Name of the Device

Trade Names:	Straumann Mini Implants
Common Name:	Endosseous Dental Implant
Classification Name:	Endosseous Dental Implant
Regulation Number:	§872.3640
Device Classification :	II
Product Code(s):	DZE
Proprietary Name:	Straumann Mini Implants

5.3 Predicate Device(s)

Primary Predicate:

- K031106 - IMTEC Sendax MDI and MDI Plus

Reference Devices:

- K083550 – Straumann Dental Implant System
- K190040 – Straumann BLX Line Extension - New Abutments
- K190662 – MRI Compatibility for Existing Straumann Dental Implant Systems

5.4 Device Description

The Straumann Mini Implants are tapered implants with an external diameter of 2.4 mm and lengths of 10, 12, and 14 mm.

Standard manufacturing processes such machining, surface treatment, cleaning, packaging and sterilization were applied for the subject devices. There are no significant changes related to the implant material, surface treatment, fundamental operating principles, sterilization processes or procedures between the subject devices and the reference devices cleared under K083550. The main difference is the Optiloc® attachment element incorporated on the top of the implant.

The implants are manufactured utilizing the Roxolid material and are finished with SLA® surface. The implant neck is machined and the Optiloc® attachment element of the implants is acting as a retention feature for dentures and it is coated using a Titanium Nitride (TiN) coating.

Straumann® Mini Implants ∅2.4 mm are suitable for oral endosteal implantation in the upper and lower jaw of fully or partially edentulous patients.

The implants can be placed with immediate function when good primary stability is achieved. The Straumann Mini Implants are intended for the stabilization of removable dentures. The removable dentures are connected to the Mini Implants through the incorporated Optiloc® attachment element.

5.5 Indications for Use

Straumann® Mini Implants ∅2.4 mm are suitable for oral endosteal implantation in the upper and lower jaw of fully or partially edentulous patients. The implants can be placed with immediate function when good primary stability is achieved. Straumann® Mini Implants are intended for the stabilization of removable dentures.

5.6 Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in Table 1. The Indications for Use for the subject devices differs from the primary predicate (K031106) with respect to the indication for inter-radicular transitional applications. The subject devices are not indicated for inter-radicular transitional applications, however, the remaining indications are equivalent.

The reference predicate K190662 is included for reference to all MRI compatibility. The reference predicate K190040 is included for reference to the TiN coating on the Straumann BLX Novaloc Abutments (for clarity only this portion of the cleared Indications for Use Statement for K190040 is included in Table 1).

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	K191895	K031106	K083550	K190040
Indications for Use	Straumann® Mini Implants ø2.4 mm are suitable for oral endosteal implantation in the upper and lower jaw of fully or partially edentulous patients. The implants can be placed with immediate function when good primary stability is achieved. Straumann® Mini Implants are intended for the stabilization of removable dentures.	The MDI and MDI PLUS are self-tapping titanium threaded screws indicated for long-term intra-bony applications. Additionally, the MDI may also be used for inter-radicular transitional applications. These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full partial edentulism, and employing minimally invasive surgical intervention.	Straumann® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental implants can also be used 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 elements (abutments). When placing implants in the posterior region, we recommend using only large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases. Specific indications for small diameter (Ø3.3 mm) implants: Because of their reduced mechanical stability, small diameter implants are only used in cases with a low mechanical load. Placement in the molar region is not recommended.	Straumann BLX Novaloc Abutments The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants.
Implant Diameter	2.4 mm	2.4 mm	3.3 mm	The reference device is not an implant

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	K191895	K031106	K083550	K190040
Implant Length	10, 12, 14 mm	10, 13, 15, 18 mm	8, 10, 12, 14, 16 mm	The reference device is not an implant
Material	Roxolid	Ti-6Al-4V	Roxolid	Ti-6Al-4V
Coating	TiN coated	No coating	No coating	TiN coated
Surface Treatment	SLA	Not available	SLA	Partially anodized
Abutment-to-restoration connection	Anchor ball	O-Ball	Screw retained	Snap-on feature
Type of recommended restoration	Stabilization of removable dentures	Stabilization of removable dentures	Support for prosthetic devices, crowns, bridges and overdentures	Attachment of full or partial dentures on dental implants
Sterilization Method	Gamma irradiation	No information available	Gamma irradiation	Not provided sterile

Table 1 – Comparison of subject device versus predicate/reference devices

5.7 Performance Testing

Insertion torque testing and wear testing 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 demonstrated the Straumann Mini Implants are equivalent to the predicate and reference devices.

The purpose of the insertion torque test is to check that the Straumann Mini Implants and the related cutting instruments make it possible to reach a suitable implant insertion torque. The average value of insertion torque measurements for each bone plate density and each implant length are within the define acceptance criteria. Wear testing is performed to evaluate the performance of the Optiloc® attachment element with regard to its retention properties. The retention force loss of the Optiloc® blue ring on Straumann Mini Implants passed the acceptance criteria.

No new issues of biocompatibility are raised for the subject devices. The Roxolid material was previously cleared per K083550 and the TiN coating was previously cleared per K190040.

The sterilization process for the Straumann Mini Implants as recommended in the labeling was 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 subject devices are sterilized 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 according to the standard cited above. The validation method used was the over kill bioburden method in accordance with ISO 11137-2:2013, *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*.

The subject devices are single use and are provided sterile. The shelf life is five years. Shelf life determination has been conducted in real time and accelerated (according to ASTM F 1980 - *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*) samples. The subject devices will not be marketed as non-pyrogenic. The method used to make the determination that the device meets pyrogen limit specifications is LAL Endotoxin Analysis. The testing limit is 20 EU/device.

Dynamic fatigue testing was conducted according to ISO 14801, *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants* and 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"*. The tests were conducted in ambient air at room temperature and demonstrated the Straumann Mini Implants are equivalent to the primary predicate devices.

5.8 Conclusion

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