July 08, 2021

Institut Straumann AG
% Jennifer Jackson
Director, Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K211052
Trade/Device Name: Straumann RidgeFit Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: April 8, 2021
Received: April 9, 2021

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211052

Device Name

Straumann® RidgeFit Implants

Indications for Use *(Describe)*

Straumann® RidgeFit Implants ø2.4 mm are for oral endosteal implantation in the upper and/or lower jaw of fully edentulous patients. The implants can be placed with immediate function when primary stability is achieved for all implants or with conventional loading if primary stability is not achieved for all implants. Straumann® RidgeFit Implants are intended for the stabilization of removable dentures.

- For mandibular restorations, at least 4 Straumann® RidgeFit Implants ø2.4 mm should be placed.
- For maxillary restorations, at least 6 Straumann® RidgeFit Implants ø2.4 mm should be placed.

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.

510(k) Summary

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
Date of Submission:	July 8, 2021

Name of the Device

Trade Names:	Straumann® RidgeFit Implants
Common Name:	Endosseous dental implant (21 CFR 872.3640)
Classification Name:	Endosseous dental implant (21 CFR 872.3640)
Regulation Number:	§872.3640
Device Classification:	II
Product Code(s):	DZE
Classification Panel:	Dental

Predicate Device(s)

Primary Predicate:

- K191895 - Straumann® Mini Implants

Traditional 510(k) Submission

Straumann® RidgeFit Implants

510(k) Summary

Device Description

The Straumann® RidgeFit Implants are tapered implants manufactured from Roxolid (TiZr) with a finished SLA surface. The implant neck is machined with an Optiloc® attachment portion resulting in a one-piece implant system acting as a retention feature for dentures, this feature is coated in a Titanium Nitride (TiN) coating. The Straumann® RidgeFit Implants have an external diameter of 2.4 mm and are available in implant lengths 10 mm, 12 mm and 14 mm with a gingival height of 2.8 mm and implant lengths 10 mm and 12 mm for gingival heights 3.8 mm and 4.8 mm. The Straumann® RidgeFit Implants are identical to the Straumann® Mini Implants cleared under K191895 apart from proposed labeling changes. Note for US Markets, Straumann has identified Straumann® Mini Implants as Straumann® RidgeFit Implants to distinguish it from other markets, this change has been documented through Memo to File. The purpose of this traditional 510(k) is to propose labeling changes to the cleared indications and the addition of contraindications to the existing devices cleared under K191895.

Intended Use

The Straumann® RidgeFit Implants are intended for the stabilization of removable dentures. The removable dentures are connected to the RidgeFit Implants through the incorporated Optiloc® attachment element.

Indications for Use

Straumann® RidgeFit Implants Ø2.4 mm are for oral endosteal implantation in the upper and/or lower jaw of fully edentulous patients. The implants can be placed with immediate function when primary stability is achieved for all implants or with conventional loading if primary stability is not achieved for all implants. Straumann® RidgeFit Implants are intended for the stabilization of removable dentures.

- For mandibular restorations, at least 4 Straumann® RidgeFit Implants Ø2.4 mm should be placed.
- For maxillary restorations, at least 6 Straumann® RidgeFit Implants Ø2.4 mm should be placed.

Technological Characteristics

The Straumann® RidgeFit Implants are identical to the Straumann® Mini Implants cleared under K191895 apart from proposed labeling changes under this submission. The purpose of this traditional 510(k) is to propose changes to the cleared indications and to add additional contraindications to the devices cleared under K191895. The technological characteristics of the subject devices are compared to the primary predicate devices in Table 1.

FEATURE	SUBJECT DEVICES	PRIMARY PREDICATE DEVICES
K Number	K211052	K191895
Indications for Use	Straumann® RidgeFit Implants Ø2.4 mm are for oral endosteal implantation in the upper and/or lower jaw of fully edentulous patients. The implants can be placed with immediate function when primary stability is achieved for all implants or with conventional loading if primary stability is not achieved for all implants. Straumann® RidgeFit Implants are intended for the stabilization of removable dentures. • For mandibular restorations, at least 4 Straumann® RidgeFit Implants Ø2.4 mm should be placed. • For maxillary restorations, at least 6 Straumann® RidgeFit Implants Ø2.4 mm should be placed.	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.
Implant Diameter	2.4 mm	2.4 mm
Implant Length	10, 12, 14 mm	10, 12, 14 mm
Gingival heights	2.8 mm	2.8, 3.8 and 4.8 mm
Material	Roxolid (TiZr)	Roxolid (TiZr)
Coating	TiN coated	TiN coated
Surface Treatment	SLA	SLA
Abutment-to-restoration connection	Anchor Ball	Anchor Ball
Recommended restoration	Stabilization of removable dentures	Stabilization of removable dentures
Sterilization Method	Gamma Irradiation	Gamma Irradiation

Table 1 – Comparison of the Subject and the Primary Predicate Devices

Performance Testing

The following performance data support the substantial equivalence determination.

Sterilization Validation and Shelf Life

The Straumann® RidgeFit Implants are single patient devices, are provided sterile via gamma irradiation at a dose of 25 kilogray (2.5 Mrad) Minimum and will be sterilized after final packaging. A sterility assurance level (SAL) of 10^{-6} has 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*. The validation method used was the VDmax 25method in accordance with *ISO 11137-2:2013, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*. The sterilization validation and shelf life data have been submitted under K191895. The shelf life of the subject RidgeFit Implants is 5 years. Sterilization method and shelf life are identical to the primary predicate devices cleared under K191895.

Biocompatibility Testing

There are no changes to the materials, surface treatments, or manufacturing methods from the currently marketed predicate devices. Therefore, no new issues of biocompatibility are raised for the subject devices and no additional biocompatibility testing was required.

Electromagnetic Compatibility

There are no changes to the materials, surface treatments, or manufacturing methods from the currently marketed predicate devices. Therefore, no new issues of electromagnetic compatibility are raised for the subject devices and they can be considered MR Conditional.

Performance Testing – Bench

The RidgeFit (Mini) Implants with 2.8 mm of gingival height have been cleared under K191895. The gingival heights of 3.8 and 4.8 mm for the lengths 10 and 12mm have been introduced via Memo to File. A fatigue test on the new 4.8 mm gingival height has demonstrated a performance equivalent to the primary predicate device of the K191895.

Relevant bench testing, including insertion torque, wear, and dynamic fatigue testing, was performed and provided in K191895 in accordance with 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, Document issued on: May 12, 2004.

This submission only intends to propose changes in the labeling of the devices. The subject devices are identical to the previously cleared devices (primary predicate and Memo to File), therefore, no additional performance testing is required.

Performance Testing – Clinical

The change in the Indications for Use to specifically indicate the RidgeFit (Mini) Implants for a minimum of 4 implants in the mandible and a minimum of 6 implants in the maxilla is supported by a clinical summary article by Lemos *et al*.[1]

Conclusion

The documentation submitted in this premarket notification demonstrates the Straumann® RidgeFit Implants are substantially equivalent to the primary predicate.

[1] Lemos CA, Verri FR, Batista VE, Júnior JF, Mello CC, Pellizzer EP. Complete overdentures retained by mini implants: A systematic review. J Dent. 2017 Feb; 57:4-13. Doi: 10.1016/j.jdent.2016.11.009. Epub 2016 Nov 22.