August 12, 2025

Institut Straumann AG
℅ Jennifer Jackson
Senior Director of Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K250294
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: January 31, 2025
Received: July 17, 2025

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K250294

Device Name

Straumann® RidgeFit Implants

Indications for Use *(Describe)*

Straumann® RidgeFit Implants ∅ 2.4 mm are indicated for oral endosteal implantation in the fully edentulous mandible and/or maxilla for the stabilization of removable dentures. 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 on all implants.

- Mandibular restorations require at least 4 Straumann® RidgeFit Implants ∅ 2.4 mm.
- Maxillary restorations require at least 6 Straumann® RidgeFit Implants ∅ 2.4 mm.

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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Traditional 510(k) Submission

Straumann® RidgeFit Implants

K250294 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:	Ninda Syam, PhD RA & Compliance Manager Institut Straumann AG Phone number: +41619651411
Date Prepared:	August 12, 2025

Name of the Device

Trade Names:	Straumann® RidgeFit 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:

- *K211052- Straumann® RidgeFit Implants*

Reference Devices:

- *K191895 - Straumann® Mini Implants*
- *K031106 - IMTEC Sendax MDI and MDI Plus Endosseous Implant*

Device Description

The Straumann® RidgeFit Implants are tapered implants manufactured from Roxolid® (Titanum-Zirconium alloy, TiZ) with a finished SLA surface. The implant neck is machined with an Optiloc® attachment portion, which is coated in Titanium Nitride (TiN) coating, resulting in a one-piece implant system acting as a retention feature for dentures. 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 ø 2.4 mm are suitable for oral endosteal implantation in the upper and lower jaw of fully edentulous patients. Conventional loading is recommended if primary stability cannot be achieved immediately on all implants.

Indications for Use

Straumann® RidgeFit Implants ø 2.4 mm are indicated for oral endosteal implantation in the fully edentulous mandible and/or maxilla for the stabilization of removable dentures. 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 on all implants.

- Mandibular restorations require at least 4 Straumann® RidgeFit Implants ø 2.4 mm.
- Maxillary restorations require at least 6 Straumann® RidgeFit Implants ø 2.4 mm.

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 on the following table.

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

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE 1	REFERENCE DEVICE 2	EQUIVALENCE DISCUSSION
K Number	K250294	K211052	K191895	K031106*	
Intended Use	Straumann® RidgeFit Implants are intended for oral implantation to provide a support structure for connected prosthetic devices.	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.	The Straumann® Mini Implants are intended for the stabilization of removable dentures.	Information not available	Similar. The subject device has essentially the same intended use and Optiloc® connection for the removable dentures as the predicate device. The last sentence of Intended Use in K211052 was removed in the subject device for wording adaptation reasons.
Indications for Use	Straumann® RidgeFit Implants Ø 2.4 mm are indicated for oral endosteal implantation in the fully edentulous mandible and/or maxilla for the stabilization of removable dentures. 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 on all implants. • Mandibular restorations require at least 4 Straumann® RidgeFit Implants Ø 2.4 mm. • Maxillary restorations require at least 6 Straumann® RidgeFit Implants Ø 2.4 mm.	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.	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.	Similar. The subject device has a more limited indication, which is only for fully edentulous patients compared to the reference device 1 (K191895), which is for fully and partially edentulous ones. Other than this, the indication of the subject device is similar to the predicate device (K211052) and reference device 1 (K191895). Additionally, new bench tests and comparisons of engineering drawings provide evidence that the subject device is substantially equivalent to the primary predicate device (K211052) and the reference device 1 (K191895).

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE 1	REFERENCE DEVICE 2	EQUIVALENCE DISCUSSION
K Number	K250294	K211052	K191895	K031106*	
Implant Diameter	2.4 mm	2.4 mm	2.4 mm	2.4 mm	Identical to K031106, K191895 and K211052.
Implant Length	10, 12, 14 mm	10, 12, 14 mm	10, 12, 14 mm	10, 13, 15, 18 mm	Identical to K191895 and K211052. Similar to K031106.
Number of cutting flutes	2	3	3	0	Substantially equivalent to K191895 and K211052. Even though there is one flute fewer in the subject device compared to the predicate device and reference device 1, their global geometry and dimensions stay the same. Data from performance testing (see discussion further below) show that the subject device has substantially equivalent performance to the predicate device and reference device 1.
Depth of cutting flutes	Average: 0.43mm	Average: 0.52mm	Average: 0.52mm	Information not available	Substantially equivalent to K191895 and K211052. Even though the depth of the cutting flutes of the subject device is reduced by 18% compared to the predicate device and reference device 1 in general, their global geometry and dimensions stay the same. Data from performance testing (see discussion further below) show that the subject device has substantially equivalent performance to the predicate device and reference device 1.
Depth of thread at the	Constant/uniform Average: 0.33mm	Varying/non-uniform Average: 0.37mm	Varying/non-uniform Average: 0.37mm	Information not available	Substantially equivalent to K191895 and K211052.

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE 1	REFERENCE DEVICE 2	EQUIVALENCE DISCUSSION
K Number	K250294	K211052	K191895	K031106*	
apical implant tip					Even though the depth of the thread at the tip of the subject device is reduced by 11% compared to the predicate device and reference device 1 in general, their global geometry and dimensions stay the same. Data from performance testing (see discussion further below) show that the subject device has substantially equivalent performance to the predicate device and reference device 1.
Material	Roxolid® (TiZr alloy)	Roxolid® (TiZr alloy)	Roxolid® (TiZr alloy)	Ti-6Al-4V	Identical to K191895 and K211052.
Neck Height	2.8, 3.8, 4.8 mm	2.8, 3.8, 4.8 mm	2.8 mm	2.5 mm	Identical to K211052. The neck heights 3.8 and 4.8 mm were introduced via a Memo-to-File to K191895.
Coating	TiN coated	TiN coated	TiN coated	Uncoated	Identical to K191895 and K211052.
Surface Treatment	SLA	SLA	SLA	Information not available	Identical to K191895 and K211052.
Abutment to Restoration Connection	Anchor ball	Anchor ball	Anchor ball	O-ball	Identical to K191895 and K211052.
Type of Recommended Restoration	Stabilization of removable dentures (Optiloc®)	Stabilization of removable dentures (Optiloc®)	Stabilization of removable dentures (Optiloc®)	Stabilization of removable dentures	Identical to K191895 and K211052.
Sterilization Method	Gamma irradiation	Gamma irradiation	Gamma irradiation	Information not available	Identical to K191895 and K211052.

*K031106 IMTEC Sendax MDI AND MDI Plus Endosseous Implant was acquired by 3M™ ESPE™ after its 510(k) clearance and is known since then as 3M™ ESPE™ MDI Mini Dental Implants with several variants, e.g., Ø2.4 mm 13 mm.

Materials

The Straumann® RidgeFit Implants are made from Roxolid® (Titanium and 13-17% Zirconium alloy), finished with SLA surface (sandblasted, large grit, acid-etched surface treatment), and integrated with Optiloc® attachment element (machined and TiN coated).

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.
- Insertion torque and Torque-to-failure test were conducted and demonstrated the subject devices are substantially equivalent to the primary predicate device.
- K211052 and K191895 (Institut Straumann AG) referenced for biocompatibility evaluation in accordance with *ISO-10993-1:2018 Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process* and the biocompatibility evaluation flowchart according 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, issue on September 8, 2023*.
- K211052 and K191895 (Institut Straumann AG) referenced for sterilization validation 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*," using the $VD_{max}25$ method.
- K211052 and K191895 (Institut Straumann AG) referenced for the packaging stability study and shelf-life study in accordance with ISO 11607-1: 2019, ASTM F1886, ASTM F1929, and ASTM F88.

- Non-clinical testing and MRI simulations were conducted, and demonstrate that these devices are MR Conditional.

Conclusion

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