June 22, 2023

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

Re: K223083
Trade/Device Name: Straumann® SLActive® labeling changes
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: DZE
Dated: May 26, 2023
Received: May 26, 2023

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 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)*
K223083

Device Name
Straumann® SLActive® labeling changes

Indications for Use *(Describe)*

Straumann® BLX Dental Implants, SLActive®

Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients.

They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.

Straumann® TLX Dental Implants, SLActive®

Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.

Other Straumann® Tissue Level and Bone Level Dental Implants, SLActive®

Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients.

Unless stated in specific indications, they can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.

Specific indications for use:

Straumann® Roxolid® Bone Level Tapered Implant Ø 2.9 mm

The Straumann® Roxolid® Bone Level Tapered implants Ø 2.9 mm are indicated for single-unit reconstruction of incisors in the lower jaw and lateral incisors in the upper jaw.

Straumann® Roxolid® Standard Plus 4 mm Short Implants

Straumann® Roxolid® Standard Plus 4 mm Short Implants are indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone 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.

Straumann® Roxolid® Standard Plus 4 mm Short Implants are specifically indicated for:

- Fixed denture prosthesis/splinted units (one implant per unit).
- Pontic cases in combination with at least one longer implant.
- Fully edentulous cases with at least one Straumann® Roxolid® Standard Plus 4 mm Short Implants in combination with 2 longer implants in the anterior region and at least four total implants.

Titanium Ø 3.3 mm implants

Ø3.3 mm S and SP RN implants are to be used only for the following indications:

Partially dentate jaws with implant-borne, fixed constructions: combine with a Ø4.1 mm implants and splint the superstructure.

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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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 Institut Straumann AG Peter Merian-Weg 12 4052 Basel, Switzerland.
Contact Person:	Jennifer M. Jackson, MS, RAC Sr. Director, Regulatory Affairs and Quality Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Prepared By:	Camila da Silva Esteves External Consultant
Date of Submission:	June 21, 2023

Name of the Device

Trade Names:	Straumann® SLActive® labeling changes
Common Name:	Endosseous Dental Implant
Classification Name:	Endosseous Dental Implant
Regulation Number:	§872.3640
Device Classification:	II
Product Code(s):	DZE
Classification Panel:	Dental
Proprietary Name:	Straumann® SLActive®

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

Predicate Device(s)

Primary Predicate:

- K171784 – Straumann Dental Implant System

Reference Devices:

- K083550 – Straumann Dental Implant System
- K111357 – Straumann Narrow Neck CrossFit (NNC) 03.3mm Dental Implant System
- K121131 – BL, 04.1mm RC, SLActive® 8mm, TiZr and 10mm, 12, 14mm
- K122855 – TL 04.1mm RN, S, SLActive® TiZr 6, 8, 10, 12, 14, 16mm Dental Implants
- K140878 – Straumann Bone Level Tapered Implant
- K153758 – Straumann Bone Level Tapered Implant
- K162890 – BLT 02.9mm SC, SLA or SLActive®, RXD, Loxim, SC Closure Cap and Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments
- K173961 – Straumann BLX Implant System
- K181703 – Straumann BLX Line Extension – Implants, SRAs and Anatomic Abutments
- K191256 – Straumann BLX Ø3.5 mm Implants
- K200586 – Straumann TLX Implant System
- K210855 – Straumann TLX Implant System
- K202942 – Straumann 4 mm Short Implants
- K212533 – BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants
- K123784 - Straumann Dental Implant System

Device Description

The SLActive® Implants from the Straumann® Dental Implants System includes:

SLActive® and Roxolid®, Standard, Ø3.3 RN, 8, 10, 12, 14, and 16 mm

SLActive® and Roxolid®, Standard, Ø4.1 RN, 6, 8, 10, 12, 14, and 16 mm

SLActive® and Roxolid®, Standard, Ø4.8 RN, 6, 8, 10, 12, and 14 mm

SLActive® and Roxolid®, Standard, Ø4.8 WN, 6, 8, 10, and 12 mm

SLActive® and Roxolid®, Standard Plus, Ø3.3 NNC, 8, 10, 12, and 14 mm

SLActive® and Roxolid®, Standard Plus, Ø3.3 RN, 8, 10, 12, and 14 mm

SLActive® and Roxolid®, Standard Plus, Ø4.1 RN and Ø4.8 RN, 6, 8, 10, 12, and 14 mm

SLActive® and Roxolid®, Standard Plus, Ø4.8 WN, 6, 8, 10 and 12 mm

SLActive® and Roxolid®, Bone Level, Ø3.3 NC, Ø4.1 RC, and Ø4.8 RC, 8, 10, 12, and 14 mm

SLActive® and Roxolid®, Bone Level Tapered, Ø2.9 SC 10, 12 and 14 mm

SLActive® and Roxolid®, Bone Level Tapered, Ø3.3 NC, Ø4.1 RC, and Ø4.8 RC, 8, 10, 12, 14, 16 and 18 mm

SLActive® and Roxolid®, BLX, Ø3.5 RB, 8, 10, 12, 14, 16, 18 mm

SLActive® and Roxolid®, BLX, Ø3.75 RB, Ø4.0 RB, Ø4.5 RB and Ø5.0 RB, 6, 8, 10, 12, 14, 16, 18 mm

SLActive® and Roxolid®, BLX, Ø5.5 WB and Ø6.5 WB, 6, 8, 10, 12, 14 and 16 mm

SLActive® and Roxolid®, Standard, TLX, Ø3.75 NT, Ø3.75 RT, Ø4.5 NT and Ø4.5 RT, 6, 8, 10, 12, 14, 16 and 18 mm

SLActive® and Roxolid®, Standard, TLX, Ø5.5 WT and Ø6.5 WT, 6, 8, 10 and 12 mm

SLActive® and Roxolid®, Standard Plus, TLX, Ø3.75 NT, Ø3.75 RT, Ø4.5 NT and Ø4.5 RT, 6, 8, 10, 12, 14, 16 and 18 mm

SLActive® and Roxolid®, Standard Plus, TLX, Ø5.5 WT and Ø6.5 WT, 6, 8, 10 and 12 mm

SLActive® and Roxolid®, Standard Plus Short, Ø4.1 RN and Ø4.8 RN and WN, 4 mm

4 mm Short Implants

All listed dental implants have already been cleared under the reference devices 510(k)s.

Intended Use

Straumann® dental implants and abutments are intended for oral implantation to provide a support structure for connected prosthetic devices.

Indications for Use

<u>Straumann® BLX Dental Implants, SLActive®</u>

Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients.

They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.

Straumann® TLX Dental Implants, SLActive®

Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.

Other Straumann® Tissue Level and Bone Level Dental Implants, SLActive®

Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients.

Unless stated in specific indications, they can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.

Specific indications for use

Straumann® Roxolid® Bone Level Tapered Implant Ø 2.9 mm

The Straumann® Roxolid® Bone Level Tapered implants Ø 2.9 mm are indicated for single-unit reconstruction of incisors in the lower jaw and lateral incisors in the upper jaw.

Straumann® Roxolid® Standard Plus 4 mm Short Implants

Straumann® Roxolid® Standard Plus 4 mm Short Implants are indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone 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.

Straumann® Roxolid® Standard Plus 4 mm Short Implants are specifically indicated for:

Fixed denture prosthesis/splinted units (one implant per unit).

Pontic cases in combination with at least one longer implant.

Fully edentulous cases with at least one Straumann® Roxolid® Standard Plus 4 mm Short Implants in combination with 2 longer implants in the anterior region and at least four total implants.

Titanium Ø 3.3 mm implants

Ø3.3 mm S and SP RN implants are to be used only for the following indications:

Partially dentate jaws with implant-borne, fixed constructions: combine with a Ø4.1 mm implants and splint the superstructure.

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in the following tables:

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICES
K Number	K223083	K171784	K083550, K111357, K121131, K122855, K140878, K153758, K162890, K173961, K181703, K191256, K200586, K202942, K210855, K212533, K123784
Material	Titanium – Zirconium alloy	Titanium – Zirconium alloy Titanium Grade 4	Titanium-Zirconium alloy
Surface Treatment	SLActive® - Hydrophilic, sandblasted, large grit, acid etched.	SLActive® - Hydrophilic, sandblasted, large grit, acid etched.	
Implant to Abutment Connection	TorcFit® CrossFit® SynOcta®	SynOcta® CrossFit®	TorcFit® CrossFit® SynOcta®
Implant Diameter	2.9mm, 3.3mm, 3.5mm, 3.75mm, 4.0mm, 4.1mm, 4.5mm, 4.8mm, 5.0mm, 5.5mm, 6.5mm	3.3mm, 4.1mm and 4.8mm	2.9mm, 3.3mm, 3.5mm, 3.75mm, 4.0mm, 4.1mm, 4.5mm, 4.8mm, 5.0mm, 5.5mm, 6.5mm
Implant Length	4, 6, 8, 10, 12, 14, 16 and 18mm	6, 8, 10, 12, 14, 16 and 18mm	4, 6, 8, 10, 12, 14, 16 and 18mm
Implant Design	Tissue level (parallel and fully tapered wall) Bone level (parallel, tapered and fully tapered wall)	Tissue level (parallel wall) Bone level (parallel and tapered wall)	Tissue level (parallel and fully tapered wall) Bone level (parallel, tapered and fully tapered wall)

Table 1 – Comparison of subject device versus primary predicate device

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

Labeling Changes and Performance Testing

The labelling changes that are being presented in this 510(k) were evaluated according to the FDA guidance document “Deciding When to Submit a 510(k) for a Change to an Existing Device”.

The proposed 510(k) does not intend to introduce new implants neither to modify cleared implants design. The purpose of this premarket notification is to revise the labeling to describe that the results of recent clinical studies on outcomes of SLActive implants in smokers are encouraging (Alsahhaf, 2019, Xiao, 2021, Chen 2017, Sener 2010, Luongo 2016). The proposed claim is supported by a literature review. In addition, changes to the Indications for Use wording were done, as well as general changes to the Instructions for Useto reflect the state-of-the-art of Straumann implant systems data and to improve the readability and clarity of the content without affecting the safety or effectiveness of the devices. Table 2 shows the substantial equivalence discussion for the proposed Indications for Use against the previously approved verbiage.

The presented Indications for Use are equivalent to the primary predicate and reference devices. The differences in the wording do not change the application of the devices. All indications allow for implant placement in the jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information in some Indications for Use was relocated to the device description for better understanding. The use of 4 or more implants for fully edentulous patients is common knowledge and was removed from some Indications for Use. The new specific Indications for Use for ∅3.3 mm implants provide more details on the recommended clinical procedure. Additionally, the section Precaution of the Instructions for Use brings attention to the use of narrow implants in the molar region.

Table 2 Indications for Use comparison table

* for the purpose of this table, the acronym IFU refers to Instructions for Use

K NUMBER	PROPOSED INDICATIONS FOR USE	PRIMARY PREDICATE DEVICE INDICATIONS FOR USE (K171784)	REFERENCE PREDICATE DEVICE INDICATIONS FOR USE	EQUIVALENCE DISCUSSION
K083550	IFU: 704333 Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. Unless stated in specific indications, they can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. **Titanium Ø 3.3 mm implants** Ø3.3 mm S and SP RN implants are to be used only for the following indications: Partially dentate jaws with implant-borne, fixed constructions: combine with a Ø4.1 mm implants and splint the superstructure.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference predicate - K083550: Straumann® ROXOLID dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® ROXOLID 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 functions. 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.	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding. The use of 4 or more implants for fully edentulous patients is common knowledge and were removed from the indications for use. The new specific Indications for Use for Ø 3.3 mm implants provides more details on the recommended clinical procedure. Additionally, the section Precaution of the IFU show brings attention to the use in molar region.

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

K NUMBER	PROPOSED INDICATIONS FOR USE	PRIMARY PREDICATE DEVICE INDICATIONS FOR USE (K171784)	REFERENCE PREDICATE DEVICE INDICATIONS FOR USE	EQUIVALENCE DISCUSSION
K111357	IFU 704333 Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. Unless stated in specific indications, they can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. **Titanium Ø 3.3 mm implants** Ø3.3 mm S and SP RN implants are to be used only for the following indications: Partially dentate jaws with implant-borne, fixed constructions: combine with a Ø4.1 mm implants and splint the superstructure.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K111357: Straumann® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. 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 components (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. **Small Diameter Implants (Ø 3.3 mm)** Because of their reduced mechanical stability, small diameter implants are only used in cases with low mechanical load. Placement in the moral region is not recommended.	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding. The use of 4 or more implants for fully edentulous patients is common knowledge and were removed from the indications for use. The new specific Indications for Use for Ø 3.3 mm implants provides more details on the recommended clinical procedure. Additionally, the section Precaution of the IFU show brings attention to the use in molar region.

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

K NUMBER	PROPOSED INDICATIONS FOR USE	PRIMARY PREDICATE DEVICE INDICATIONS FOR USE (K171784)	REFERENCE PREDICATE DEVICE INDICATIONS FOR USE	EQUIVALENCE DISCUSSION
K121131	IFU 704333 Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. Unless stated in specific indications, they can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K121131: The 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 specified). Straumann® dental implants can 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 are single crown, bridges and partial or full denture, 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.	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding. The use of 4 or more implants for fully edentulous patients is common knowledge and were removed from the indications for use.

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Straumann® SLActive® Labeling Changes

510(k) Summary

K NUMBER	PROPOSED INDICATIONS FOR USE	PRIMARY PREDICATE DEVICE INDICATIONS FOR USE (K171784)	REFERENCE PREDICATE DEVICE INDICATIONS FOR USE	EQUIVALENCE DISCUSSION
K122855	IFU 704333 Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. Unless stated in specific indications, they can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K122855: 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 implants 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 corresponding elements (abutments). When placing implants in the posterior region, we recommend using only larger diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediate loaded cases.	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding. The use of 4 or more implants for fully edentulous patients is common knowledge and were removed from the indications for use.

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Straumann® SLActive® Labeling Changes

510(k) Summary

K NUMBER	PROPOSED INDICATIONS FOR USE	PRIMARY PREDICATE DEVICE INDICATIONS FOR USE (K171784)	REFERENCE PREDICATE DEVICE INDICATIONS FOR USE	EQUIVALENCE DISCUSSION
K140878	IFU 704333 Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. Unless stated in specific indications, they can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K140878: 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 through the corresponding components (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding. The use of 4 or more implants for fully edentulous patients is common knowledge and were removed from the indications for use.

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

K NUMBER	PROPOSED INDICATIONS FOR USE	PRIMARY PREDICATE DEVICE INDICATIONS FOR USE (K171784)	REFERENCE PREDICATE DEVICE INDICATIONS FOR USE	EQUIVALENCE DISCUSSION
K153758	Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. Unless stated in specific indications, they can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K153758 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 through the corresponding components (abutments).	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding. The new specific Indications for Use for Ø 3.3 mm implants provides more details on the recommended clinical procedure. Additionally, the section Precaution of the IFU show brings attention to the use in molar region

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

K NUMBER	PROPOSED INDICATIONS FOR USE	PRIMARY PREDICATE DEVICE INDICATIONS FOR USE (K171784)	REFERENCE PREDICATE DEVICE INDICATIONS FOR USE	EQUIVALENCE DISCUSSION
K162890	IFU 704333 Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. Unless stated in specific indications, they can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. **Straumann® Roxolid® Bone Level Tapered Implant Ø 2.9 mm** The Straumann® Roxolid® Bone Level Tapered implants Ø 2.9 mm are indicated for single-unit reconstruction of incisors in the lower jaw and lateral incisors in the upper jaw.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K162890 Straumann® Bone Level Tapered Implants Ø 2.9 mm are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and aesthetic oral rehabilitation of patients with missing teeth. Straumann® Bone Level Tapered Implants Ø 2.9 mm 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 are connected to the implants through the corresponding components (abutments). The Straumann® Bone Level Tapered Implants Ø 2.9 mm are indicated for reconstruction of missing incisors in the lower jaw and lateral incisors in the upper jaw.	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding. The specific indications for Ø 2.9 mm implants are the same as the reference device.

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

K NUMBER	PROPOSED INDICATIONS FOR USE	PRIMARY PREDICATE DEVICE INDICATIONS FOR USE (K171784)	REFERENCE PREDICATE DEVICE INDICATIONS FOR USE	EQUIVALENCE DISCUSSION
K173961	IFU 702110 Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K173961 Straumann® BLX Implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. BLX Implants can be placed with immediate function on single-tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding abutment components.	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The single-tooth restoration would be the worst case due to the higher masticatory load. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding.
K181703	IFU 702110 Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K181703 Straumann® BLX Implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. BLX Implants can be placed with immediate function on single-tooth, bar and bridge applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding abutment components.	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The single-tooth restoration would be the worst case due to the higher masticatory load. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding.

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

K NUMBER	PROPOSED INDICATIONS FOR USE	PRIMARY PREDICATE DEVICE INDICATIONS FOR USE (K171784)	REFERENCE PREDICATE DEVICE INDICATIONS FOR USE	EQUIVALENCE DISCUSSION
K191256	IFU 702110 Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K191256 Straumann® BLX Implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. BLX Implants can be placed with immediate function on single-tooth, bar and bridge applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants by the corresponding abutment components.	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The single-tooth restoration would be the worst case due to the higher masticatory load. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding.

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

K NUMBER	PROPOSED INDICATIONS FOR USE	PRIMARY PREDICATE DEVICE INDICATIONS FOR USE (K171784)	REFERENCE PREDICATE DEVICE INDICATIONS FOR USE	EQUIVALENCE DISCUSSION
K200586	IFU 704450 Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K200586 Straumann® TLX Implants are suitable for endosteal implantation in the upper and lower jaws and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. TLX Implants can be placed with immediate function on single-tooth and multi-unit restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding abutment components.	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding.

K202942	IFU 704333 Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. Unless stated in specific indications, they can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. **Straumann® Roxolid® Standard Plus 4 mm Short Implants** Straumann® Roxolid® Standard Plus 4 mm Short Implants are indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone 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. Straumann® Roxolid® Standard Plus 4 mm Short Implants are specifically indicated or: • Fixed denture prosthesis/splinted units (one implant per unit). • Pontic cases in combination with at least one longer implant. • Fully edentulous cases with at least two Straumann® Roxolid® Standard Plus 4 mm Short Implants in combination with 2 longer implants in the anterior region.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K202942 Straumann® 4 mm Short Implants are indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone 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 denture prosthesis/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.	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding. The specific indication for 4mm Short implants is the same as the reference predicate.
K210855	IFU 702110	Straumann® Dental implants are indicated for oral endosteal	Reference Predicate – K210855	**Equivalent**

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

K NUMBER	PROPOSED INDICATIONS FOR USE	PRIMARY PREDICATE DEVICE INDICATIONS FOR USE (K171784)	REFERENCE PREDICATE DEVICE INDICATIONS FOR USE	EQUIVALENCE DISCUSSION
	Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function	implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	The Straumann® BLX Implants are suitable for oral and endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® BLX implants can 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).	All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding.
K212533	IFU 702110 Straumann® dental implants are indicated for functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are 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 are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	Reference Predicate – K212533 The Straumann® BLX Implants are suitable for oral and endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® BLX implants can 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).	**Equivalent** All indications allow for implant placement in jaw, providing support for single-tooth or multiple-tooth and allowing for immediate loading when good primary stability is achieved. The prosthetic restorations information was not excluded from the Instructions for Use but relocated to the device description for better understanding.

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

The design of the subject implants has already been reviewed under the referenced predicate and reference device 510(k)s. The subject implants are provided sterile via gamma irradiation and are sterilized after final packaging. The sterilization process for the subject implants as recommended in the labeling was validated to a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11137-1, "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 (or $VD_{max25)}$ method in accordance with ISO 11137- 2, "Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose". The shelf life is 5 years.

The subject implants will not be marketed as non-pyrogenic. 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 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.

Biological assessment has been 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', Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016" for each of the subject devices.

The subject implants have obtained the status of MR Conditional per K180540. The MR Conditional tests were conducted according to FDA's Guidance "*Testing and Labeling Medical Devices for Safety in Magnetic Resonance (MR) Environment*".

Dynamic fatigue assessment 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". The test covers permanent restoration of the implants without failure.

Insertion tests were performed for the subject implants and showed that there is an adequate insertion torque in different bone classes when the implant is inserted according to the surgical procedure.

K223083 – Traditional 510(k)

Straumann® SLActive® Labeling Changes

510(k) Summary

No significant changes have been performed to the subject implants since clearance so previously cleared bench data continue to be representative of the performance of the subject implants.

For smokers' claim, a systematic literature search was performed to identify available data from studies where SLActive implants were placed in smokers. In 5 publications, 251 SLActive implants were placed in 237 patients with an age range of 25-65 years old. Published studies reported on titanium or titanium zirconium-alloy implants with SLActive surfaces and diameters ranging from 3.3 – 4.8 mm and lengths 8 – 12 mm. In the publications, adverse events such as failure to osseointegrate, peri-implantitis, spinning of implant during surgery, mobility of implant during surgery, late failure of implant, severe and mild bone loss, loosening of abutment, paresthesia, acrylic/porcelain chipping were reported. Adverse events were not reported at a higher rate in smokers compared to non-smokers. Additionally, implant failure rates were not found to be significantly different in smoking compared to non-smoking patients with SLActive implants.

Conclusion

This 510(k) does not intend to introduce new implants neither to modify cleared implants design. The documentation submitted in this premarket notification demonstrates the **Straumann® SLActive® labeling changes** are substantially equivalent to the primary predicate and reference devices.

References:

Alsahhaf A, Alshagroud RS, Al-Aali KA, Alofi RS, Vohra F, Abduljabbar T. Survival of Titanium-Zirconium and Titanium Dental Implants in Cigarette-smokers and Never-smokers: A 5-Year Follow-up. Chin J Dent Res. 2019;22(4):265-272. doi: 10.3290/j.cjdr.a43737. PMID: 31859286.

Xiao W, Chen Y, Chu C, Dard MM, Man Y. Influence of implant location on titanium-zirconium alloy narrow-diameter implants: A 1-year prospective study in smoking and nonsmoking populations. J Prosthet Dent. 2022 Aug;128(2):159-166. doi: 10.1016/j.prosdent.2020.09.051. Epub 2021 Feb 5. PMID: 33551139.

Chen Y, Man Y, Clinical Evaluation of SLActive Titanium-zirconium narrow diameter implants for anterior and posterior crowns in smokers and non-smokers group. In proceedings from ITI World Symposium, 4-6 May 2017, Basel, Switzerland, Abstract 045