9/14/23

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

Re: K230108
Trade/Device Name: Straumann® BLC and TLC Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: August 10, 2023
Received: August 11, 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,

Sherrill Lathrop Blitzer

for Andrew 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:

K230108

Device Name

Straumann® BLC and TLC Implants

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒Prescription Use (Part 21 CFR 801 Subpart D) ☐Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

5 510(k) Summary – K230108

5.1 Submitter's Contact Information

Submitter:	Straumann USA, LLC (on behalf of Institut Straumann AG) 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: 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 & Alternate Contact:	Corinne Arimatea Regulatory Affairs and Compliance Manager Institut Straumann AG Phone number: +41 61 965 1217
Date of Submission:	September 14, 2023

5.2 Name of the Device

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

5.3 Predicate Device(s)

Primary Predicate:

- *K150938 – Straumann® Dental Implant System – Roxolid® SLA Implants*

Reference Devices:

- *K173961 - Straumann BLX Implant System*
- *K210855 - Straumann BLX Implant System*
- *K212533 - BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants*
- *K200586 - Straumann TLX Implant System*
- *K153758 - Straumann Bone Level Tapered Implants*

5.4 Device Description

The subject devices are part of the Straumann® Dental Implant System, which is an integrated system of endosseous dental implants with corresponding abutments and healing components as well as instruments and prosthetic parts. Straumann® dental implants are solid screw implants with a bone anchorage surface that is large-grit sandblasted and acid-etched. In addition, SLActive® is in a chemically activated state, which is preserved by storage in a saline solution (NaCl). Straumann® dental implants can be used following the extraction or loss of natural teeth to restore chewing function. The prosthetic restorations supported are single crowns, bridges and partial or full dentures, which are connected to the implants using the corresponding abutments.

The BLC and TLC implants features the TorcFit connection and are available in the maximum endosteal outer diameters ø 3.3 mm, ø 3.75 mm, ø 4.5 mm, ø 5.5 mm and ø 6.5 mm.

The BLC implants are available with the following length options:

- L 8 mm to L 18 mm for the maximum endosteal outer diameter ø 3.3 mm,
- L 6 mm to L 18 mm for diameters ø 3.75 mm and ø 4.5 mm
- L 6 mm to L 16 mm for diameter ø 5.5 mm
- L 6 mm to 14 mm for diameter ø 6.5 mm.

The subject BLC implants are presented with RB (Regular Base) and WB (Wide Base) prosthetic platform.

A summary of the diameter/length implant body combinations is given in Table 1.

Implant Diameter	ø 3.3mm	ø 3.75mm	ø 4.5mm	ø 5.5mm	ø 6.5mm
Implant Length	-	6 mm	6 mm	6 mm	6 mm
	8 mm	8 mm	8 mm	8 mm	8 mm
	10 mm	10 mm	10 mm	10 mm	10 mm
	12 mm	12 mm	12 mm	12 mm	12 mm
	14 mm	14 mm	14 mm	14 mm	14 mm
	16 mm	16 mm	16 mm	16 mm	-
	18 mm	18 mm	18 mm	-	-
Prosthetic platforms	RB	RB	WB	WB	WB

Table 1 – Overview of diameter/length implant body combinations for BLC implants

The TLC implants are available with the following length options:

- L 8 mm to L 18 mm for the maximum endosteal outer diameter ø 3.3 mm,
- L 6 mm to L 18 mm for diameters ø 3.75 mm and ø 4.5 mm
- L 6 mm to L 12 mm for diameter ø 5.5 mm
- L 6 mm to 10 mm for diameter ø 6.5 mm.

The subject TLC implants are presented with the NT (Narrow TorcFit) RT (Regular TorcFit) WT (Wide TorcFit) prosthetic platform. The implant neck is available either as Standard (2.8 mm height) or Standard Plus (1.8 mm height) option.

A summary of the diameter/length implant body combinations is given in Table 2.

Implant Diameter	ø 3.3mm	ø 3.75mm	ø 4.5mm	ø 5.5mm	ø 6.5mm
Implant Length	-	6 mm	6 mm	6 mm	6 mm
	8 mm	8 mm	8 mm	8 mm	8 mm
	10 mm	10 mm	10 mm	10 mm	10 mm
	12 mm	12 mm	12 mm	12 mm	-
	14 mm	14 mm	14 mm	-	-
	16 mm	16 mm	16 mm	-	-
	18 mm	18 mm	18 mm	-	-
Prosthetic platforms	NT / RT	NT / RT	RT / WT	WT	WT

Table 2 – Overview of diameter/length implant body combinations for TLC implants

5.5 Intended Use

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

5.6 Indications for Use

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.

5.7 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 DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	K230108	K150938	K173961	K210855	K212533	K153758
Indications for Use	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 and for the functional and esthetic 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 elements (abutments).	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.	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 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 used are connected to the implants through the corresponding abutment components.	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 and for the functional and esthetic 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 primary predicate 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).

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	K230108	K150938	K173961	K210855	K212533	K153758
Material	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)
Surface Treatment	Hydrophilic SLActive® and SLA®	Hydrophilic SLA®	Hydrophilic SLActive®	Hydrophilic SLActive® and SLA®	Hydrophilic SLActive® and SLA®	Hydrophilic SLActive®
Implant to Abutment Connection	TorcFit (with conical fitting)	Narrow CrossFit (NC) Regular CrossFit (RC) Narrow Neck CrossFit (NNC) Regular Neck (RN) Wide Neck (WN)	TorcFit (with conical fitting)	TorcFit (with conical fitting)	TorcFit (with conical fitting)	Narrow CrossFit® (NC) Regular CrossFit® (RC)
Implant Diameter	Ø 3.3, 3.75, 4.5, 5.5, 6.5 mm	Ø 3.3, 4.1, 4.8 mm	Ø 4.5, 5.5, 6.5 mm	Ø 3.75 and 4.0 mm	Ø 5.0, 5.5, 6.5 mm	Ø 3.3, 4.1, 4.8 mm
Implant Length	Ø 3.3: 8, 10, 12, 14, 16, 18 mm Ø 3.75 and 4.5: 6, 8, 10, 12, 14, 16, 18 mm Ø 5.5: 6, 8, 10, 12, 14, 16 mm Ø 6.5: 6, 8, 10, 12, 14 mm	8, 10, 12, 14 and 16 mm	Ø 4.5: 6 to 18 mm Ø 5.5 and 6.5: 6 to 12 mm	6 mm	Ø 5.0: 18 mm Ø 5.5 and 6.5: 14 and 16 mm	18 mm
Implant Design	Apically tapered Bone Level implant	Parallel wall and Apically tapered Bone Level implant (BLT)	Fully tapered Bone Level implant	Fully tapered Bone Level implant	Fully tapered Bone Level implant	Apically tapered Bone Level implant (BLT)
Thread Pitch	0.8, 0.9, 1 and 1.15 mm	0.8 and 1.25 mm	2.0 to 2.8 mm	1.7 to 1.8 mm	2.5 to 3.1 mm	0.8 mm
Sterilization Method	Irradiation	Irradiation	Irradiation	Irradiation	Irradiation	Irradiation

Table 3 – Comparison of subject device versus primary predicate and reference device – BLC implant

Traditional 510(k) Submission

Straumann® BLC and TLC Implants

510(k) Summary

	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	K230108	K150938	K200586	K153758
Indications for Use	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 and for the functional and esthetic 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 elements (abutments).	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.	Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic 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 primary predicate 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).
Material	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)
Surface Treatment	Hydrophilic SLActive® and SLA®	Hydrophilic SLA®	Hydrophilic SLActive®	Hydrophilic SLActive®
Implant to Abutment Connection	TorcFit (with conical fitting)	Narrow CrossFit (NC) Regular CrossFit (RC) Narrow Neck CrossFit (NNC) Regular Neck (RN) Wide Neck (WN)	TorcFit (with conical fitting)	Narrow CrossFit® (NC) Regular CrossFit® (RC)
Implant Diameter	Ø 3.3, 3.75, 4.5, 5.5, 6.5 mm	Ø 3.3, 4.1, 4.8 mm	Ø 3.75, 4.5, 5.5, 6.5 mm	Ø 3.3, 4.1, 4.8 mm
Implant Length	Ø 3.3: 8, 10, 12, 14, 16, 18 mm Ø 3.75 and 4.5: 6, 8, 10, 12, 14, 16, 18 mm Ø 5.5: 6, 8, 10, 12 mm Ø 6.5: 6, 8, 10 mm	6, 8, 10, 12, 14, 16 mm	Ø 3.75, 4.0, 4.5, 5.0 mm: 6, 8, 10, 12, 14, 16, 18 mm Ø 5.5 and 6.5 mm: 6, 8, 10, 12 mm	18 mm
Implant Design	Apically tapered Tissue Level implant	Parallel wall and Apically tapered Bone Level implant	Fully tapered Tissue Level implant	Apically tapered Bone Level implant

	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	K230108	K150938	K200586	K153758
Implant neck	Tulip shape	Tulip shape n/a (bone level)	Tulip shape	n/a (bone level)
Prosthetic platform	NT, RT and WT	NC, RC, NNC, RN, and WN	NT, RT and WT	NC and RC
Thread Pitch	0.8, 0.9, 1 and 1.15 mm	0.8 and 1.25 mm	1.7, 2.0, 2.1, 2.2, 2.5, 2.6, and 2.8 mm	0.8 mm
Sterilization Method	Irradiation	Irradiation	Irradiation	Irradiation

Table 4 – Comparison of subject device versus primary predicate and reference device – TLC implant

The Indications for Use of the primary predicate and subject devices are identical. Both devices are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients, with identical use. The Indications for Use of the primary predicate device includes details of prosthetic restoration, whereas for the subject devices, those details are provided in the Product Description section.

The subject devices have identical or equivalent technological characteristics compared to the primary predicate and reference devices. The material, surface treatment, sterilization method, and implant characteristics (length, diameter & connection) are identical to the primary predicate and reference devices. The device performance demonstrates substantial equivalence between subject devices and primary predicate/reference devices.

5.8 Performance Testing

Sterilization Validation and Shelf-life

The subject devices are provided sterile via gamma irradiation at a dose of 25 kGy and will be sterilized after final packaging. The sterilization process for the subject devices as recommended in the labeling was validated to a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11137-1:2006, "Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, 2006-04-05". The validation method used was the over kill bioburden (or VDmax25) method in accordance with ISO 11137- 2:2013, "Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose". There are no changes to the sterilization procedures or processes from those of the Straumann primary predicate devices (K150938), the subject devices do not represent a higher challenge to the sterilization process in comparison to the validated worst-case product and validated irradiation sterilization process.

The packaging of the subject device is equivalent to the packaging of the primary predicate and reference device. The shelf life for devices provided sterile is 5 years.

The devices 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.

Biocompatibility Testing

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 devices are equivalent in material, surface, manufacturing processes, sterilization process, body contact and contact duration to the reference device K210855 therefore, no new issues regarding biocompatibility were raised.

Electromagnetic Compatibility

There are no significant changes to the materials and dimensions 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.

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".

Performance Testing – Bench

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. The test was conducted in saline (2 Hz and 37°C) at 2 million cycles covering permanent restoration of the implant without failure.

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

A comparison of the bone-to-implant contact (BIC) and pull-out force between the subject implants and previously cleared devices (K150938) was performed.

- As part of the BIC evaluation, the nominal endosseous surface area of the subject devices was calculated and then compared to the contact surface area of the reference devices. The analysis concludes that the acceptance criterion is met; the subject devices have a larger endosseous surface area, and therefore, more area of bone-to-implant contact compared to the corresponding reference device.

- To determine the pull-out force, the implants were inserted in bone substitute material and then pulled-out while the resistance was measured. The analysis concludes that the acceptance criterion is met; the subject devices have a higher pull-out force compared to the corresponding reference device.

The subject devices were analyzed using scanning electron microscopy and light microscopy to investigate the apical end of the implant body after removal from the packaging. All the inspected implants showed a uniform breaking surface, with no residual metal fragments at the broken tip area.

The subject device surface treatments are identical to the surface treatments of the primary predicate and reference devices cleared under K150938, K173961, K210855, K212533, K200586 and K153758. The SLA® surface treatment is a sand-blasted, large grit, acid etched surface. The SLActive® surface treatment is a sand-blasted, large grit, acid etched, chemically active and hydrophilic surface. The surface is routinely tested by roughness measurement or scanning electron microscopy.

Conclusion

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