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

June 5, 2018

Re: K173961
Trade/Device Name: Straumann® BLX Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 30, 2018
Received: May 1, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

forTina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173961

Device Name
Straumann® BLX Implant System

Indications for Use *(Describe)*

Straumann® BLX Implants
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 Closure Caps and Healing Abutments
Straumann® Closure Caps and Healing Abutments are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and to shape, maintain and stabilize the soft tissue during the healing process. Closure caps and healing abutments should be used only with suitable implant connections. Straumann Closure Caps and Healing Abutments have a maximum duration of usage of 6 months.

Straumann® BLX Basal Screws and Temporary Abutments
Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they may not be placed into occlusion. Final abutments may be placed into occlusion when the implant is fully osseointegrated. BLX Temporary Abutments have a maximum duration of usage of 180 days.

Straumann® BLX Variobases
Straumann® Variobase® prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The prosthetic restoration (crowns) can be cemented onto the Straumann® Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they must be placed out of occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. All digitally designed copings and/or crowns for use with the Straumann® Variobase® Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5 510(k) Summary

5.1 Submitter's Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: 1-978-747-2509

Fax Number: 1-978-747-0023

Contact Person: Jennifer M. Jackson, MS

Prepared by: Ana Carolina Martins Vianna

Viviana Horhoiu

Date of Submission: June 5, 2018

5.2 Name of the Device

Trade Names: Straumann® BLX Implant System

Common Name: Endosseous Dental Implant

Classification Name: Endosseous Dental Implant

Regulation Number: 21 CFR 872.3640

Classification: Class II

Product Codes: Primary product code: DZE

Secondary product code: NHA

5.3 Predicate Device(s)

Primary Predicate:

- K150182 – Neodent Implant System – CM Drive Implants

Reference Devices:

- K122855 TL 04.1mm RN,S, SLAcitve TiZr 6, 8, 10, 12, 14, 16mm Dental Implants
- K033922 – Device Modification ITI® Dental Implants

- K162890 - BLT 02.9mm SC, SLA or SLActive, RXD, Loxim, SC Closure Cap and Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutment.
- K101545 – Genesis Implant System
- K153624 – Neodent Implant System
- K170838 – Medentika TiBases
- K130808 – Straumann Healing Abutments, Healing Caps, and Closure Screws
- K092814 - Straumann NC Temporary Abutments
- K120822 - Straumann® CARES® Variobase™ Abutments
- K170354 - Straumann Variobase Abutments
- K142890 - Straumann Variobase Abutment NNC, Straumann Variobase Abutment RN, Straumann Variobase Abutment WN, Straumann Variobase Abutment NC, Straumann Variobase Abutment RC, IPS e.max CAD MO Coping, IPS e.max CAD LT Crown, IPS e.max CAD HT Crown, coron CoCr Single Unit

5.4 Device Description

The Straumann BLX Implants are fully tapered implants manufactured utilizing the Roxolid material and are finished with SLActive® surface. The connection is identified as conical fitting with Torx style engaging feature. The prosthetic platforms are identified as RB (Regular Base) and WB (Wide Base). The implants with a RB platform have a “small top/head”, and implants with WB platform have a “large top/head”, whereas the internal connection is identical for both platform and all the implant diameters and lengths. They are available in the following sizes:

Platform	Neck Ø (mm)	Maximium outer Ø (mm)	Length (mm)
RB	3.5	4.5	6
			8
			10
			12
			14
			16
			18
WB	4.5	5.5	6
			8

			10
			12
		6.5	6
			8
			10
			12

The closure cap and healing abutments are manufactured from Titanium Grade 4, per ISO 5832-2 and ISO 5832-11, and are anodized signal violet for the parts compatible with the RB platform and brown for the parts compatible with the WB platform for identification purposes. Closure caps are screwed into the implant to protect the inner configuration and shoulder of the implant during the healing phase in cases of submerged (submucosal) healing. Healing abutments are screwed into the implant to protect the inner configuration in cases of transmucosal healing and are placed out of occlusion. They are available in the following sizes:

Closure Caps:

Platform	**Gingival heights (mm)**
RB/WB	0.4
WB	0.5

Healing Abutments:

Platform	**Ø (mm)**	**Gingival heights (mm)**	**Abutment heights (mm)**
RB/WB	4.0	1.5	2
			4
		2.5	2
			4
RB/WB	5.0	1.5	2
			4
		2.5	2
			4
WB	6.0	0.75	2
			4
		1.5	2
			4

Platform	Ø (mm)	Gingival heights (mm)	Abutment heights (mm)
RB/WB	6.5	1.5	2
			4
		2.5	2
			4
		3.5	2
			4
WB	7.5	0.75	2
			4
		1.5	2
			4

The temporary abutments are manufactured from TAN and are anodized signal violet (RB platform) and brown (WB platform) for identification purposes. The temporary abutments are fixed in the implant with a basal screw which is also manufactured from TAN. The basal screw will be delivered with the temporary abutment. They are available in the following sizes:

Platform	Ø (mm)	Gingival heights (mm)	Chimney height (mm)
RB/WB	3.8	1.5	10
		2.5	
RB/WB	4.5	1.5	
		2.5	
RB/WB	6.0	2.5	
		3.5	
WB	5.5	0.75	
		1.5	

BLX Variobase abutments is a two-piece abutment ultimately composed by three components:

- Variobase™ Abutment (Ti-base)
- Prosthetic restoration (coping and/or crown)
- Basal Screw

The BLX Variobase Abutments are manufactured and are delivered with the corresponding basal screw. The prosthetic restoration (crowns) can be cemented onto the Variobase prosthetic components. They are available in the following sizes:

Platform	Ø (mm)	Gingival heights (mm)	Chimney height (mm)
RB/WB	3.8	1.5	5.5
		2.5	
RB/WB	4.5	1.5	
		2.5	
WB	5.5	0.75	
		1.5	

The BLX Variobase Abutments will be marketed as a stand-alone component or through the CARES® X-Stream™ workflow (prosthetic restoration designed and manufactured through CARES® Visual/validated Straumann milling and then shipped together with the Straumann® BLX Variobase® Abutment and basal screw in the same shipment). All digitally designed copings and/or crowns for use with the BLX Variobase Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

Prosthetic Restoration Design and Materials

- Digital materials:
  - IPS e.max CAD MO, LT or HT
  - polycon® ae (for temporary restorations)

The manufacturing of the coping and/or crown should follow the standard procedure according to the material manufacturer's instructions for use.

For digital materials, the following range of modifications is recommended:

	IPS e.max CAD	polycon® ae
Minimum Wall Thickness	0.7	0.5
Minimum angulation	0°	0°
Maximum angulation	30°	30°

Basal screws are used to seat the temporary abutments and the BLX Variobase Abutments to the dental implant, and can be also be used during lab procedures to fix lab prosthetic parts on implant analogs. There is one basal screw for the RB platform and one for the WB platform. They have identical designs and differ only in color-coding (signal violet and brown) to ease the handling. They are provided along the abutments but they are also provided as standalone screws. The BLX basal screws are manufactured from TAN.

5.5 Indications for Use

Straumann® BLX Implants

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 Closure Caps and Healing Abutments

Straumann® Closure Caps and Healing Abutments are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and to shape, maintain and stabilize the soft tissue during the healing process. Closure caps and healing abutments should be used only with suitable implant connections. Straumann Closure Caps and Healing Abutments have a maximum duration of usage of 6 months.

Straumann® BLX Basal Screws and Temporary Abutments

Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they may not be placed into occlusion. Final abutments may be placed into occlusion when the implant is fully osseointegrated.

BLX Temporary Abutments have a maximum duration of usage of 180 days.

Straumann® BLX Variobases

Straumann® Variobase® prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The prosthetic restoration (crowns) can be cemented onto the Straumann® Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they must be placed out of occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. All digitally designed copings and/or crowns for use with the Straumann® Variobase® Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

5.6 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		EQUIVALENCE DISCUSSION
	Subject Device – BLX Implants	**K150182 Neodent Implant System**	**K122855 Straumann Implant System**	**K101545 Genesis Implant System**	
Indications for Use	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.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Straumann® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental Implants can also be used for Immediate or early, Implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the Implants by the corresponding elements (abutments). When placing implants in the posterior region, we recommend using only large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.	The Genesis Implant System is intended for use in single-stage or two-stage surgical procedures in all types of bone in partially or fully edentulous mandibles and maxillae. The Genesis Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis implants are intended for placement following natural tooth loss or for immediate placement into an extraction socket. Immediate function may be achieved when good primary stability is established and appropriate occlusal loading is applied.	The subject implants have the same indication as the primary predicate device K150182. Only minor differenes in wording that do not affect the intended use.
Material	Titanium-13 Zirconium alloy (Roxolid®)	Ti Grade 4	Titanium-13 Zirconium alloy (Roxolid®)	Ti Grade 4	Identical to reference device K122855.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICES		EQUIVALENCE DISCUSSION
	Subject Device – BLX Implants	**K150182 Neodent Implant System**	**K122855 Straumann Implant System**	**K101545 Genesis Implant System**	
Surface Treatment	Hydrophilic SLActive®	Neoporos and Acqua (hydrophilic)	Hydrophilic SLActive®	Hydrophilic surface enriched with calcium and phosphorous ions	Identical to the primary prediate.
Implant to Abutment Connection	BLX (with conical fitting)	CM (with conical fitting)	Synocta (with conical fitting)	TiLobe™	The subject devices have a conical implant-to-abutment fitting as well as K150182 and K122855 devices, nevertheless, each implant system has its own engaging feature in the conical connection.
Implant Diameter	Ø 4.5, 5.5, 6.5 mm	Ø 3.5, 4.3 and 5.0 mm	Ø 4.1 mm and 4.8 mm	Ø 3.8 to 6.5 mm	In the range of diameters of the primary predicate and the reference devices.
Implant Length	6 to 18 mm	18 mm	6 to 16 mm	8.5 to 18 mm	In the range of lengths of the primary predicate and the reference devices.
Implant Body	Tapered body	Tapered body	Straight body	Straight and tapered body	Identical to primary predicate and one of the reference devices.
Thread Pitch	2.0 to 2.8 mm	2.2 mm	1.25 mm	Information not available	Similar to device K150182. Both implants have threads designed to provide proper primary stability and allows for immediate loading.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICES		EQUIVALENCE DISCUSSION
	Subject Device – BLX Implants	**K150182 Neodent Implant System**	**K122855 Straumann Implant System**	**K101545 Genesis Implant System**	
Sterilization Method	Irradiation	Irradiation	Irradiation	Irradiation	Identical.

Table 1 - Comparison of subject device versus primary predicate device (Dental Implants)

FEATURE	PROPOSED DEVICE	REFERENCE PREDICATE DEVICE	EQUIVALENCE DISCUSSION
	Subject Device – BLX Healing components	**K130808**	
Material	Titanium Grade 4 according to ISO 532-2 and ISO 5832-11	Titanium Grade 4	Identical material.
Implant to Abutment Connection	BLX (with conical fitting)	Synocta CrossFit (with conical fitting)	The subject devices have a conical implant-to-abutment fitting as well as the reference devices, nevertheless, each implant system has its own engaging feature in the conical connection.
Prosthetic Platform Diameter	Closure Cap: NA Healing Abutments: Ø 4, 5, 6, 6.5 and 7.5 mm	Closure Cap: NA Healing Abutment: Ø 3.3 to 6.5 mm	Mostly into the range of the reference device diameters. 7.5 mm of diameter does not raise new safety issue.
Abutment Heights	Closure Cap: 0.4 and 0.5 mm Healing Abutments: 2.75 to 7.5 mm	Closure Cap: 0 mm and 1.5 mm Healing Abutments: 2.0 to 7.0 mm	The heights of the subject devices are mostly into the range of the reference device. Some healing abutments are 0.5mm higher in order to cover different clinical situations and do not introduce new safety issue.
Sterilization Method	Irradiation	Irradiation	Identical to the reference device.

Table 2 - Comparison of subject device versus reference device (BLX Closure Cap and BLX Healing Abutments)

FEATURE	PROPOSED DEVICE	REFERENCE PREDICATE DEVICE	EQUIVALENCE DISCUSSION
	Subject Device – BLX Temporary Abutments	**K092814 Straumann implant system**	
Material	Ti-6Al-7Nb	Ti-6Al-7Nb	Identical
Implant to Abutment Connection	BLX (with conical fitting)	CrossFit® (NC) (with conical fitting)	The subject devices have a conical implant-to-abutment fitting as well as the reference devices, nevertheless, each implant system has its own engaging feature in the conical connection.
Diameter	Ø 3.8, 4.5, 5.5 and 6 mm	Ø3.5 mm	The subject devices have larger diameters in order to match with the diameters of the new BLX implants. Larger diameters do not introduce a new worst case in terms of performance.
Gingival Heights	0.75, 1.5, 2.5 and 3.5 mm	1.0 mm	The different gingival heights are intended to cover different clinical situations and do not introduce new safety issue.
Chimney Heights	10 mm	10 mm	Identical.
Angulation	Straight	Straight	Identical.
Sterilization Method	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Identical.

Table 3 - Comparison of subject device versus reference predicate device (BLX Temporary Abutments)

FEATURE	PROPOSED DEVICE	REFERENCE PREDICATE DEVICE		EQUIVALENCE DISCUSSION
	Subject Device - BLX Variobase Abutments	**K170838 Medentika TiBases**	**K142890 and K170354 Straumann implant system**	
Material	Ti-6Al-7Nb	Ti-6Al-4V	Ti-6Al-7Nb	Identical to reference device K142890.
Implant to Abutment Connection	BLX (with conical fitting)	Several, according to the implant lines referred in the Indications for Use statement	CrossFit® (SC) (with conical fitting)	The subject devices have a conical implant-to-abutment fitting as well as the Straumann reference devices, nevertheless, each implant system has its own engaging feature in the conical connection.
Prosthetic Platform Diameter	Ø 3.8, 4.5, and 5.5 mm	Ø 3.25 to 6.0 mm	Ø 3.9 and 7.0 mm	Into the range of the reference devices.
Gingival Heights	0.75 – 2.5 mm	0.3 – 1.15 mm	2.0 and 3.0 mm	Into the range of the reference devices.
Chimney Heights	5.5 mm (can be reduced)	3.5 and 5.5 mm	3.5 and 5.5 mm	Into the range of the reference devices.
Design Workflow	Wax-up or Straumann CARES® Visual, Dental Wings software using the Straumann CARES Visual Plug-In and 3Shape	Straumann CARES System	Wax-up or Straumann CARES® Visual, Dental Wings software using the Straumann CARES Visual Plug-In and 3Shape	Identical to the Straumann reference devices.
Manufacturing Workflow	Straumann Milling	Straumann Milling	Traditional casting or pressing or Straumann Milling	Into the range of the reference devices.

FEATURE	PROPOSED DEVICE	REFERENCE PREDICATE DEVICE		EQUIVALENCE DISCUSSION
	Subject Device - BLX Variobase Abutments	**K170838 Medentika TiBases**	**K142890 and K170354 Straumann implant system**	
Coping/ Crown Material	Digital materials: IPS e.max CAD Polycon® ae	Zirconia IPS e.max CAD	Cast materials: Type 4 metals (ISO 22674) Press materials: IPS e.max® Press Ceramic Digital materials: Coron® Zerion® IPS e.max CAD n!ce Polycon® ae	Into the range of the reference devices.
Coping/ Crown Angulation	Up to 30°	Up to 30°	Up to 30°	Identical.
Sterilization Method	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Identical to the reference devices.
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Identical to the reference devices.

Table 4 - Comparison of subject device versus reference device (BLX Variobase Abutments)

5.7 Performance Testing

The following performance data were provided in support of the substantial equivalence determination.

5.7.1 Sterilization Validation and Shelf Life

The BLX implants, closure caps and healing abutments are provided sterile via gamma irradiation at a dose of 25 kilogray (2.5 Mrad) minimum. A sterility assurance level (SAL) of 10^{-6} had been validated in accordance with ISO 11137-1:2006, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, 2006-04-05*. The validation method used was the over kill bioburden method in accordance with ISO 11137-2:2013, *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*.

The BLX Temporary Abutments and BLX Variobase Abutments needs to be end-user sterilized by moist heat (steam). The recommended sterilization has been validated according to ISO 17665-1 and ISO 17665-2 and to applicable recommendations in the FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015*".

There are no changes to the sterilization procedures or processes from those of the Straumann predicate devices. The packaging of all BLX devices is equivalent to the packaging of the predicate and reference device and so the shelf life for sterile devices remains to be 5 years since the materials are not adversely affected by the time.

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.

5.7.2 Biocompatibility Testing

Biological assessment has been performed according to ISO 10993-1:2009 "*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 have the equivalent nature of body contact, contact duration, material formulation and sterilization methods compared to the primary and reference predicate devices. Differences in the manufacturing process have been assessed via Chemical Characterization and Cytotoxicity tests.

5.7.3 Bench Testing

Dynamic fatigue, static strength, insertion torque tests, pullout strength tests, surface area analysis, and bone-to-implant contact analysis were conducted according to the FDA guidance document “Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments” and demonstrated the Straumann BLX Implant System is equivalent to the predicate and reference devices.

Dynamic fatigue (and static strength) tests were performed to evaluate the fatigue load limits of the proposed Straumann BLX Implants. Based on worst case considerations, both platforms RB and WB were tested and proved equivalent to the reference devices.

Insertion torque tests were conducted on the worst case defined for each diameter (Ø4.5, Ø 5.5 and Ø 6.5 mm) of the BLX portfolio: the shortest implant (6 mm), the middle length implant (12 mm) and the longest implant (18 mm). With this test, it was demonstrated that the BLX Implants and the related cutting instruments allow reaching suitable implant insertion torques.

Pullout strength tests, surface area analysis and bone-to-implant contact analysis were performed for the 6mm long BLX implants with Ø 4.5, 5.5 and 6.5 mm and equivalency to the reference devices was demonstrated.

5.7.4 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided according to the FDA guidance documents “Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations” and “General Principles of Software Validation; Final Guidance for Industry and FDA Staff”. The software for this device was considered as a “moderate” level of concern.

Also, software implementation verification provided demonstrates that all subject Variobase devices plus the modeling components within the new BLX portfolio are suitable to work together into the defined digital workflow to produce copings or crowns that properly fit and compose the final two-piece abutment.

5.7.5 Clinical data

No device specific clinical data has been submitted to demonstrate substantial equivalence.

5.8 Conclusion

The documentation submitted in this premarket notification demonstrates the Straumann® BLX implants, BLX Closure Caps and Healing Abutments, BLX Temporary Abutments, and Variobase Abutments are substantially equivalent to the primary predicate and reference devices.