5 510(k) Summary

5.1 Submitter's Contact Information

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5.2 Name of the Device

Trade Names: Straumann® BLX Line Extension - New Abutments

Common Name: Endosseous Dental Implant Abutment

Classification Name: Endosseous Dental Implant Abutment

Regulation Number: 21 CFR 872.3630

Classification: Class II

Product Codes: NHA

5.3 Predicate Device(s)

Primary Predicate:

- K173961 – Straumann BLX Implant System

Reference Devices:

- K173968 – Straumann Variobase for Bridge/Bar Cylindrical
- K173379 – Straumann Variobase for Crown AS
- K173902 – Neodent Implant System - GM Line
- K172798 – Straumann CARES Abutments CoCr
- K151157 – Straumann Variobase Abutment for Bars/Bridges

- K150899 – Straumann® CARES Titanium Alloy (TAN) Abutment

5.4 Indications for Use

Straumann BLX Healing Abutments for Bars and Bridges

Straumann 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 form, maintain and stabilize the soft tissue during the healing process.

Healing abutments should be used only with suitable implant connections.

Healing components have a maximum duration of usage of 6 months.

Straumann BLX Temporary Abutments for Bars and Bridges

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 Variobase Abutments for Bar and Bridges

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 (bridge or overdenture) can be cemented on the Straumann® Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. They may not be placed into occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated.

Straumann BLX Variobase Abutments AS

The Straumann Variobase for Crown AS is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase for Crown AS are indicated for screw retained single tooth or cement-retained single tooth

and bridge restorations. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Temporary restorations are indicated to be placed out of occlusion. All digitally designed copings and/or crowns for use with the Straumann Variobase for Crown AS are intended to be sent to Straumann for manufacture at a validated milling center.

Straumann BLX Novaloc Abutments

The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants.

Straumann BLX CARES Abutments

The Straumann CARES Abutments are indicated for single tooth replacement and multiple tooth restorations.

The prosthetic restoration can be cemented or directly veneered/screw-retained.

5.5 Device Description

BLX Healing Abutments for Bars and Bridges

Healing abutments are screwed into the implant in cases of transmucosal healing to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. They are placed out of occlusion and have a maximum duration of usage of 180 days.

Unlike the predicate RB/WB healing abutments (K173961), the subject healing abutments are intended to shape the soft tissue for posterior placement of bridge restorations instead of single crowns. The subject healing abutments are manufactured from Titanium Grade 4 and are anodized in violet.

BLX Temporary Abutments for Bars and Bridges

Temporary Abutments are intended to be placed into Straumann dental implants to provide support for temporary restorations. 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, as well as provide a temporary esthetic solution. They support

a temporary restoration and may not be placed into of occlusion. Straumann BLX Temporary Abutments have a maximum duration of usage of 180 days.

Unlike the predicate RB/WB temporary abutments (K173961), the subject temporary abutments are intended to shape the soft tissue for posterior placement of bridge restorations instead of single crowns. The subject temporary abutment cannot be shortened. The Temporary abutment for bar/bridge is a non-engaging device intended to support multiple-unit restoration. The subject temporary abutment is manufactured from TAN and is anodized in violet.

The temporary abutments are fixed in the implant by means of a basal screw which is also manufactured from TAN.

BLX Variobase Abutments for Bars and Bridges

Variobase Abutments for Bars and Bridges are intended to be placed into Straumann implants to provide support for multi-unit restorations. The prosthetic restoration (bar/bridge) must be cemented onto the Variobase abutments, which is then screwed onto the implants. 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.

Unlike the predicate Variobase abutments (K173968), the subject Variobase abutments present 3 retention features in the chimney instead of 4. The Variobase abutments for bar/bridges are non-engaging devices intended to support multiple-unit restorations. The subject Variobase abutments are manufactured from TAN and are anodized in violet.

The Variobase abutments are fixed in the implant by means of a basal screw which is also manufactured from TAN.

BLX Variobase Abutments AS for Crowns

Variobase abutments AS for crowns are intended to be placed into Straumann implants to provide support for single-unit restorations. The prosthetic restoration (crown) must be cemented onto the Variobase abutment, which is then screwed onto the implant. 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.

The Variobase abutments are manufactured from TAN and are anodized in violet or in brown according to the compatible BLX implant platform (RB/WB or RB).

Unlike the predicate Variobase abutments (K173961/K173379), the subject Variobase abutments present 3 retention features in the chimney instead of 4. The chimney presents a cutout window to facilitate the handling of the screw driver in an angulated position. The Variobase abutments AS for crown are engaging devices intended to support single-unit restorations. The Variobase abutments are fixed in the implant by means of a basal screw which is also manufactured from TAN.

The Variobase abutments for crown AS are titanium bases to be used as the lower part of two-piece abutments. The upper part of the two-piece abutment is a CAD/CAM designed and manufactured restoration. The planning and milling of the customized restoration must be made using the validated Straumann CARES Visual, Dental Wings software using the Straumann CARES Visual Plug-In. All digitally designed copings and/or crowns for use on the Variobase abutments are intended to be manufactured at a validated milling center.

BLX Novaloc Abutments

Novaloc Abutments are intended to be placed into Straumann dental implants to provide support for full arch detachable restorations (over-denture).

The Novaloc abutments are manufactured from TAV (Ti-6Al-4V, Titanium-Aluminum-Vanadium) and are anodized in violet. The restoration is connected to the Novaloc abutment through a snap-on fixture provided by a negative shape of Novaloc snap-on fixture embedded into the final restoration. The snap-on feature is TiN coated.

Unlike the reference Novaloc abutments (K173902), the subject Novaloc abutments are not only provided in a straight version but also angulated.

The Novaloc abutments are provided non-sterile with instructions for end user sterilization.

Angled models: are composed of an abutment body with a coupled basal screw. They are engaging devices.

Straight models: both body and thread parts are machined in one piece. They are non-engaging devices.

BLX CARES Abutments

CARES Abutments are intended to be placed into Straumann implants to provide support for prosthetic reconstructions such as crowns and bridges. The final abutment, fabricated from a pre-milled blank, is designed to allow for individual customization regarding function and esthetics.

The blank, manufactured from TAN and CoCr, is composed of a pre-milled implant-to-abutment connection (TorcFit) and a cylindrical body with enough material volume to create a wide range of geometries for the final abutment.

Inside the abutment, a screw channel provides access to the internal thread feature of the implant, such that the component can be firmly attached while providing fit between screw, abutment and implant.

The planning and milling of the customized restoration must be made using the validated Straumann CARES Visual, Dental Wings software using the Straumann CARES Visual Plug-In. The maximum angulation allowed is 30° and the minimum wall thickness allowed is 0.4 mm. All digitally designed abutments are intended to be manufactured at a validated milling center.

BLX Basal Screws

Basal screws are used to fix abutments to dental implant, and can also be used during lab procedures to fix lab prosthetic parts on implant analogs. They are provided along the abutments and also provided as standalone screws.

The subject Basal Screws are manufactured from TAN.

The Basal Screw for Variobase AS is anodized in green since this color identifies Straumann devices pertaining to AS system.

5.6 Technological Characteristics

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

Healing Abutments for Bars and Bridges

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE
	Subject Device	**K173961**
Indications for Use	Straumann 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 form, maintain and stabilize the soft tissue during the healing process. Healing abutments should be used only with suitable implant connections. Healing components have a maximum duration of usage of 6 months.	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.
Material	Titanium Grade 4	Titanium Grade 4
Implant to Abutment Connection	BLX (with conical fitting)	BLX (with conical fitting)
Diameter	4.5 and 5.5 mm	4.0 to 7.5 mm
Gingival height	1.5 mm	1.5 to 3.5 mm
Abutment height	2 to 4 mm	2 to 4 mm
BLX Platform	RB/WB	RB/WB WB
Sterilization Method	Irradiation	Irradiation
Surface	Anodized	Anodized

Table 1 – Comparison matrix: subject device versus reference device (Healing Abutments for Bars and Bridges)

Temporary Abutments for Bars and Bridges

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE
	Subject Device	**K173961**
Indications for Use	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.	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.
Material	Ti-6Al-7Nb	Ti-6Al-7Nb
Implant to Abutment Connection	TorcFit connection	TorcFit connection
Diameter	4.5 mm	3.8, 4.5, 5.5 and 6 mm
Gingival height	1.5 mm	0.75, 1.5, 2.5 and 3.5 mm
Abutment height	5.5 mm	10 mm (can be shortened up to 6 mm)
BLX Platform	RB/WB	RB/WB WB
Angulation	Straight	Straight
Sterilization Method	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized
Surface	Partially anodized	Partially anodized

Table 2 – Comparison matrix: subject device versus reference device (Temporary Abutments for Bars and Bridges)

Variobase Abutments for Bars and Bridges

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE
	Subject Device	**K173968**
Indications for Use	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 (bridge or overdenture) can be cemented on the Straumann® Variobase™ prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. They may not be placed into occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated.	Straumann Variobase for Bridge/Bar Cylindrical prosthetic components directly connected to the endosseous dental implants are indicated for use as an aid in prosthetic rehabilitations. The patient-specific prosthetic restoration (bridge or overdenture) can be cemented on the Straumann Variobase for Bridge/Bar Cylindrical prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. They may not be placed into occlusion. Straumann® Variobase for Bridge/Bar Cylindrical and patient-specific restorations may be placed into occlusion when the implant is fully osseointegrated.
Material	Ti-6Al-7Nb	Ti-6Al-7Nb
Implant to Abutment Connection	TorcFit connection	CrossFit (NC)
Diameter	4.5 mm	4.5 – 7.0 mm
Abutment height	3.5 mm	3.5 – 4.5 mm
Abutment height design	3 retention features	4 retention features
Type of recommended restoration	Bars/Bridges	Bars/Bridges
Abutment Angulation	Straight	Straight
Design Workflow	Wax-up or Straumann CARES Visual, Dental Wings software using the Straumann CARES Visual Plug-In	Wax-up or Straumann CARES Visual, Dental Wings software using the Straumann CARES Visual Plug-In
Manufacturing Workflow	Digital workflow via Straumann milling center	Digital workflow via Straumann milling center
Coping/ Crown Material	Materials cleared by the FDA under 21 CFR 872.6660 or exempt materials as described under 21 CFR 872.3060 (Noble metal alloys) and 21 CFR 872.3710 (Base metal alloys)	Materials cleared by the FDA under 21 CFR 872.6660 or exempt materials as described under 21 CFR 872.3060 (Noble metal alloys) and 21 CFR 872.3710 (Base metal alloys)
Coping/ Crown Angulation	Up to 30°	Up to 30°
Sterilization Method	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized
Surface	Partially anodized	Machined

Table 3 – Comparison matrix: subject device versus reference device (Variobase Abutments for Bars and Bridges)

Variobase Abutments AS for Crowns

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
	Subject Device	K173379	K173961
Indications for Use	The Straumann Variobase for Crown AS is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase for Crown AS are indicated for screw retained single tooth or cement-retained single tooth and bridge restorations. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Temporary restorations are indicated to be placed out of occlusion. All digitally designed copings and/or crowns for use with the Straumann Variobase for Crown AS are intended to be sent to Straumann for manufacture at a validated milling center.	The Straumann Variobase for Crown AS is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase for Crown AS are indicated for screw retained single tooth or cement-retained single tooth and bridge restorations. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Temporary restorations are indicated to be placed out of occlusion. All digitally designed copings and/or crowns for use with the Straumann Variobase for Crown AS are intended to be sent to Straumann for manufacture at a validated milling center.	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 may not be placed into 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.
Material	Ti-6Al-7Nb	Ti-6Al-7Nb	Ti-6Al-7Nb
Implant to Abutment Connection	TorcFit connection	NC/RC (CrossFit)	TorcFit connection
Diameter	4.5 and 5.5 mm	3.8 mm – 7.0 mm	3.8 to 5.5 mm
Gingival height	1.5 mm	1.0 – 3.0 mm	0.75 – 2.5 mm
Abutment height	5.5 mm	3.5 mm – 6.5 mm	5.5 mm (can be reduced until 3.5 mm)
Abutment height design	Cylindrical, with cutout window	Cylindrical, with cutout window	Cylindrical, without cutout window
Type of recommended restoration	Crowns	Crowns	Crowns

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
	Subject Device	**K173379**	**K173961**
Design Workflow	Wax-up or Straumann CARES Visual, Dental Wings software using the Straumann CARES Visual Plug-In	Straumann CARES Visual	Wax-up or Straumann CARES Visual, Dental Wings software using the Straumann CARES Visual Plug-In
Manufacturing Workflow	Digital workflow via Straumann milling center	Traditional casting or pressing or Straumann Milling	Digital workflow via Straumann milling center
Coping/ Crown Material	Zerion LT	Cast materials: - Type 4 metals (ISO 22674) - Base metal alloys (e.g., cobalt-chromium (CoCr)) - Noble metal alloys (e.g., gold alloy) Press materials: - IPS e.max® Press Ceramic Digital materials: - coron® - zerion® LT - polycon® ae - zerion ML - zerion UTML - IPS e.max® CAD Ceramic - n!ce	IPS e.max CAD Polycon ae
Abutment Angulation	Up to 30°	Up to 30°	Up to 30°
Sterilization Method	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized
Surface	Partially anodized	Machined	Partially anodized

Table 4 – Comparison matrix: subject device versus reference device (Variobase Abutments AS for Crowns)

Novaloc Abutments

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
	Subject Device	K173902	K173968
Indications for Use	The Straumann® Retentive System is indicated for the attachment of full or partial dentures on Straumann dental implants.	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 Variobase for Bridge/Bar Cylindrical prosthetic components directly connected to the endosseous dental implants are indicated for use as an aid in prosthetic rehabilitations. The patient-specific prosthetic restoration (bridge or overdenture) can be cemented on the Straumann Variobase for Bridge/Bar Cylindrical prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. They may not be placed into occlusion. Straumann® Variobase for Bridge/Bar Cylindrical and patient-specific restorations may be placed into occlusion when the implant is fully osseointegrated.
Material	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-7Nb
Implant to Abutment Connection	TorcFit connection	Neodent GM connection	CrossFit (NC)
Diameter	4.5 mm	3.3 mm	4.5 – 7.0 mm
Gingival height	1.5 to 6.5 mm	1.5 to 5.5 mm	NA
Abutment-to-restoration connection	Snap on feature	Snap on feature	Cement-retained
Type of recommended restoration	Multi-unit	Multi-unit	Multi-unit
Abutment Angulation	0 and 15°	Straight	Straight
Sterilization Method	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized
Surface	Partially anodized / TiN coated	TiN coated	Machined

Table 5 – Comparison matrix: subject device versus reference device (Novaloc Abutments)

CARES Abutments

FEATURE	PROPOSED DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
	Subject Device	**K172798**	**K150899**
Indications for Use	The Straumann CARES Abutments are indicated for single tooth replacement and multiple tooth restorations. The Straumann CARES TAN and CoCr abutment restoration can be cemented or directly veneered/screw-retained. The Straumann CARES Golden Ti/TiN abutment restoration is cement-retained.	The Straumann CARES Abutments CoCr are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/ screw-retained..	The Straumann CARES TAN abutments are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/ screw-retained.
Material	TAN CoCr	CoCr	TAN
Implant to Abutment Connection	TorcFit connection	CrossFit (NC/RC)	CrossFit (NC/RC)
Type of recommended restoration	Crowns and bridges	Crowns and bridges	Crowns and bridges
Design Workflow	Wax-up or Straumann CARES Visual, Dental Wings software using the Straumann CARES Visual Plug-In	Wax-up or Straumann CARES Visual, Dental Wings software using the Straumann CARES Visual Plug-In	Wax-up or Straumann CARES Visual, Dental Wings software using the Straumann CARES Visual Plug-In
Manufacturing Workflow	Digital workflow via Straumann milling center	Digital workflow via Straumann milling center	Digital workflow via Straumann milling center
Abutment Angulation	Up to 30°	Up to 30°	Up to 30°
Sterilization Method	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized
Surface finish	Partially anodized	Machined	Machined

Table 6 – Comparison matrix: subject device versus reference device (CARES Abutments)

5.7 Performance Testing

The following performance data support the substantial equivalence determination.

5.7.1 Sterilization Validation and Shelf Life

The BLX 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} has been validated in accordance with ISO 11137-1:2006, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a*

sterilization process for medical devices, 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 packaging of the BLX Healing abutments is equivalent to the packaging of the predicate and reference device and the shelf life is 5 years when considering that the materials are not adversely affected by time.

There are no changes to the sterilization method or processes when compared to the Straumann predicate devices.

The other subject abutments are provided non-sterile and need to be sterilized by moist heat (steam) by the end-user. The recommended sterilization method has been validated according to ISO 17665-1 and ISO 17665-2 applicable recommendations in the FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, issued on March 17, 2015".

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 equivalent nature of body contact, contact duration, material formulation and sterilization methods compared to the primary and reference devices.

5.7.3 Bench Testing

Dynamic fatigue and static strength tests 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. The test environment for the temporary abutments, Novaloc abutments, and CARES Abutments (TAN) was ambient air. The test environment for the remaining abutments was 0.9% NaCl at 37°.

5.7.4 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 subject Straumann BLX Abutments are substantially equivalent to the primary predicate and reference devices.