5 510(k) Summary

5.1 Submitter's Contact Information

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5.2 Name of the Device

Trade Names: Straumann® BLX Variobase Abutment

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 Device:

- K173961 – Straumann BLX Implant System

Reference Devices:

- K170356 – Straumann Variobase Abutments
- K162890 – Small Diameter Implant (SDI)
- K142890 – Straumann® Variobase Abutments

5.4 Device Description

BLX Variobase abutments are two-piece abutments composed of the following components:

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

The BLX Variobase abutments 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.

The BLX Variobase Abutments are manufactured from TAN (titanium-aluminum-niobium alloy) and are available in different gingiva heights and diameters. The abutments are delivered with the corresponding basal screw.

The prosthetic restoration (copings/crowns) can be cemented onto the Variobase abutment and then the set is screwed on the implant using the basal screw.

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).

The BLX Variobase abutments are cleared under K173961.

The purpose of this premarket notification is to extend the Straumann BLX Implant System portfolio with additional materials for customized restorations (upper part of the two-piece abutment) for use with the BLX Variobase abutments (lower part of the two-piece abutment).

<u>Prosthetic Restoration Design and Materials</u>

The following is an overview of the possible coping/crown materials:

- Digital materials:
  - **coron® (subject to this submission)**
  - **zerion® LT, ML or UTML (subject to this submission)**
  - IPS e.max CAD (cleared by K173961)
  - polycon® ae (for temporary restorations, cleared by K173961)

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

Basal screws are used to fix the BLX Variobase Abutments to the dental implant, and can be also 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 (violet for RB and brown for WB) to ease the handling. They are provided along the abutments but they are also provided as standalone (replacement) screws. The BLX basal screws are manufactured from TAN.

5.5 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 (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 Table 1.

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE DEVICES		
	Straumann BLX Variobase Abutment	**K173961 Straumann BLX Implant System**	**K170356 Straumann Variobase Abutments**	**K162890 Small Diameter Implant (SDI)**	**K142890 Straumann® Variobase Abutments**
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 (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.	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.	The Straumann® Variobase® Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. 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.	Straumann® SC Variobase® abutments are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented on the Straumann® SC 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. 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.	The Straumann® Variobase® Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. 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	Ti-6Al-7Nb	Ti-6Al-7Nb
Implant to Abutment Connection	BLX (with conical fitting)	BLX (with conical fitting)	CrossFit®	Small CrossFit® (SC)	CrossFit® synOcta® (RN/WN)
Prosthetic Platform Diameter	Ø 3.8 to 5.5 mm	Ø 3.8 to 5.5 mm	Ø 3.9 and 7.0 mm	Ø 3.3/4.3 mm (minor/major oval dimension)	Ø 3.9 – 7.0 mm

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Gingival Heights	0.75 – 3.5 mm	0.75 – 2.5 mm	1.0 – 3.0 mm	1.0 – 3.0 mm	1.0 – 3.0 mm
Chimney Heights	5.5 mm (can be reduced)	5.5 mm (can be reduced)	3.5 - 4.5 mm	6.7 – 8.7 mm (overall height)	3.5 – 4.5 mm
Design Workflow	Wax-up or Straumann CARES® Visual, Dental Wings software using the Straumann CARES Visual Plug-In and 3Shape	Wax-up or Straumann CARES® Visual, Dental Wings software using the Straumann CARES Visual Plug-In and 3Shape	Wax-up or CAD	Wax-up or Open CAD CARES® Visual	Wax-up or Open CAD
Abutment Angulation	Up to 30°	Up to 30°	Up to 30°	Up to 30°	Up to 30°
Manufacturing Workflow	Straumann Milling	Straumann Milling	Straumann Milling	Traditional casting or pressing or Straumann Milling	Traditional casting or pressing or Straumann Milling
Coping/ Crown Material	Digital materials: coron® zerion® LT zerion® ML and UTML	Digital materials: IPS e.max CAD polycon® ae	Digital materials: zerion® ML and UTML	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	Traditional Workflow: Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: polycon® ae (temporary) zerion® (permanent) IPS e.max® CAD Ceramic (permanent) coron® (permanent)
Sterilization Method	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized	Non-sterile/ End user sterilized

Table 1 – Comparison of subject device versus reference devices (BLX Variobase Abutments)

5.7 Performance Testing

Sterilization and Shelf Life:

The sterilization process for the BLX Variobase Abutments as recommended in the labeling was validated according to applicable recommendations in the FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015"* and according to ISO 17655-1, *Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices."*

Biocompatibility:

Biocompatibility was evaluated according to ISO 10993-1:2009 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* and the biocompatibility evaluation flow chart according to the FDA Guidance document "*Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016*" for each of the subject devices. No new issues of biocompatibility are raised for the subject devices and therefore, no additional biocompatibility testing was required.

Performance Testing Bench:

Dynamic fatigue tests for the implant-abutment system 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 according to ISO 14801, *"Dentistry -- Implants -- Dynamic loading test for endosseous dental implants"*. The test results demonstrated the Straumann® BLX Implant/Variobase final abutment system is equivalent to the predicate and reference devices. The test environment was 0.9% NaCl at 37°.

5.8 Conclusion

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