January 22, 2026

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

Re: K253315
Trade/Device Name: Straumann Variobase Abutments XC for Bridge/Bar
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 29, 2025
Received: December 23, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253315

Device Name

Straumann Variobase Abutments XC for Bridge/Bar

Indications for Use *(Describe)*

The Straumann Variobase Abutments XC for Bridge/Bar are prosthetic components placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase Abutments XC for Bridge/Bar are indicated for screw-retained or cement-retained bridge restorations. 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. Temporary restorations are indicated to be placed out of occlusion. Final abutments and restorations may be placed in occlusion when the implant is fully osseointegrated.

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.

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510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of : Institut Straumann AG Peter-Merian-Weg 12 4052 Basel, Switzerland
Contact Person:	Jennifer M. Jackson, MS Director of Regulatory Affairs and Quality Phone Number : +1-978-747-2509 Fax Number : +1-978-747-0023
Prepared By & Alternate Contact:	Olivier Russo Associate Director Regulatory Affairs Institut Straumann AG Phone number: +41 61 965 1260
Date of Submission:	January 21, 2026

Name of the Device

Trade Names:	Straumann Variobase Abutments XC for Bridge/Bar
Common Name:	Straumann Variobase Abutments XC for Bridge/Bar
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Classification :	II
Product Code(s):	NHA
Secondary Product Code:	n/a
Review Panel:	Dental
Proprietary Name:	Straumann Variobase Abutments XC for Bridge/Bar

Predicate Device(s)

Primary Predicate:

- *K190040 - Straumann® BLX Variobase Abutments for Bar and Bridges*

Reference Devices:

- *K190662 - MRI Compatibility for Existing Straumann Dental Implant Systems*
- *K230108 - Straumann® BLC and TLC Implants*

Device Description

Straumann Variobase Abutments XC 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.

The subject Variobase abutments are manufactured from Ti-6Al-7Nb (TAN) and are anodized in violet.

The Variobase Abutments for bar/bridges are non-engaging devices intended to support multiple-unit restorations.

The Variobase abutments are provided non-sterile with instructions for end user steam sterilization. The Variobase abutments are fixed in the implant by means of a basal screw which is also manufactured from Ti-6Al-7Nb (TAN). The subject Straumann Variobase Abutments XC for Bridge/Bar is provided in two different platform models, both available with straight and angled screw channel solutions :

Traditional 510(k) Submission

Straumann Variobase Abutments XC for Bridge/Bar

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Table 10.4.a - Straumann Variobase Abutments XC for Bridge/Bar characteristics

Platform	Ø (mm)	Gingival heights (mm)	Chimney height (mm)
RB/WB	3.8 / 4.5	1.5 / 2.5 / 3.5	7
WB	5.5	0.75 / 1.5	7

Intended Use

Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.

Indications for Use

The Straumann Variobase Abutments XC for Bridge/Bar are prosthetic components placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase Abutments XC for Bridge/Bar are indicated for screw-retained or cement-retained bridge restorations. 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. Temporary restorations are indicated to be placed out of occlusion. Final abutments and restorations may be placed in occlusion when the implant is fully osseointegrated.

Technological Characteristics

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

Table 10.7.a - Technological Characteristics

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE		EQUIVALENCE DISCUSSION
K Number	**K253315 - Straumann Variobase Abutments XC for Bridge/Bar**	**K190040 - Straumann® BLX Variobase Abutments for Bar and Bridges**	**K190040- BLX Variobase Abutments AS for Crown**	
Indications for Use	The Straumann Variobase Abutments XC for Bridge/Bar are prosthetic components placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase Abutments XC for Bridge/Bar are indicated for screw-retained or cement-retained bridge restorations. 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. Temporary restorations are indicated to be placed out of occlusion. Final abutments and restorations may be placed in occlusion when the implant is fully osseointegrated.	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.	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 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.	Equivalent to predicate.
Implant to Abutment Connection	<u>TorcFit connection</u> New RB/WB Interface (Flat top with internal guidance within the conical interface) New WB Interface (implant shoulder with internal guidance within the conical interface) Non-engaging design	<u>TorcFit connection</u> RB/WB Interface (sitting on implant shoulder) WB Interface (sitting on implant shoulder) Non-engaging design	<u>TorcFit connection</u> RB/WB Interface (sitting on implant shoulder) WB Interface (sitting on implant shoulder) Engaging design	Equivalent to the primary predicate. The new Variobase XC portfolio offers a new interface design. Equivalency is supported by testing fatigue.
Abutment Material	Titanium alloy (Ti-6Al-7Nb, TAN)	Titanium alloy (Ti-6Al-7Nb, TAN)	Titanium alloy (Ti-6Al-7Nb, TAN)	Identical to the primary predicate
Restoration Types Supported	Bridges and bars	Bridges and bars	Crowns	Identical to the primary predicate device
Compatible Implants	Straumann Bone Level implants having RB/WB and WB implant-to-abutment interface geometries BLX and BLC implant systems: • BLX implant diameters : 3.5 / 3.75 / 4 / 4.5 / 5 / 5.5 / 6.5 • BLC implant diameters : 3.3 / 3.7 / 4 / 4.5 / 5 / 5.5 / 6.5	Straumann Bone Level BLX implants having RB/WB implant-to-abutment interface geometries	Straumann Bone Level BLX implants having RB/WB implant-to-abutment interface geometries	Identical to the primary predicate device
Maximum Angulation	30° controlled in design software	30° controlled in design software	30° controlled in design software	Identical to the primary predicate device
Gingiva height	RB/WB Interface: 1.5 / 2.5 / 3.5 mm WB Interface: 0.75 / 1.5 mm	RB/WB Interface: 1.5 mm WB Interface: 1.5 mm	RB/WB Interface: 1.5 mm WB Interface: 1.5 mm	Equivalent to the primary predicate device. The new Variobase XC portfolio offers more flexibility with more Gingiva height available. It closes the gaps related to the missing Gingiva Heights, and harmonizes the emergence profile to the existing Variobase for Crown portfolio. The new RB/WB emergence profile is designed to be very similar to the existing Variobase for Crown portfolio. The same healing abutment can be used.

Traditional 510(k) Submission

Straumann Variobase Abutments XC for Bridge/Bar

510(k) Summary – K253315

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE		EQUIVALENCE DISCUSSION
K Number	**K253315 - Straumann Variobase Abutments XC for Bridge/Bar**	**K190040 - Straumann® BLX Variobase Abutments for Bar and Bridges**	**K190040- BLX Variobase Abutments AS for Crown**	
Variobase Abutment Chimney Height	7 mm (can be reduced to minimum 3.5 mm) Note: the abutment post height is customizable. Adaptable levels are visually identifiable on the chimney section via grooves and spaced 1 mm apart, starting from the maximum height of the Variobase abutment	5.5 mm (can be reduced to 3.5 mm)	5.5mm	Equivalent to the primary predicate device. The new Variobase XC portfolio offers more flexibility at the chimney height.
Variobase platform diameter range	RB, WB Interface: 3.8 / 4.5 mm WB Interface: 5.5 mm	4.5 mm	Ø 4.5mm and 5.5mm	Identical to the primary predicate
Screw Channel	Straight and Angled screw channel	Straight screw channel	Angled screw channel solutions	Identical to the primary predicate
Surface	Partially anodized Roughened and structured chimney surface (laser-texturized)	Partially anodized	Partially anodized	Identical to the primary predicate for the anodized surface. Roughened surface enhancing cement retention compared to currently available Variobase abutments was evaluated through biocompatibility testing and pull-off testing. These assessments support the demonstration of substantial equivalence to the predicate device. SEM/EDX analysis was performed to evaluate the surface characteristics.
Sterility	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Identical to the primary predicate

Performance Testing

Sterilization Validation and Shelf Life

The Straumann Variobase Abutments XC for Bridge/Bar subject devices are provided non-sterile and need to be sterilized by moist heat (steam) after milling into the patient-specific shape by the end-user. The recommended sterilization method has been validated according to ISO 17665-1 and applicable recommendations in the FDA guidance document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015”. The sterilization methods and parameters are equivalent to the primary predicate and reference devices.

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 and manufacturing processes to the primary predicate and reference devices, 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. *K190662 - MRI Compatibility for Existing Straumann Dental Implant Systems* was referenced for MRI testing and labelling.

Performance Testing – Bench

Dynamic Fatigue

The device design and performance testing submitted or referenced in support of this premarket notification 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 are representative of the design and performance of the subject devices.

Pull-off Testing

The Straumann Variobase Abutments XC for Bridge/Bar feature a roughened and structured chimney surface, which improves cement retention compared to the machined surface of current Variobase abutments. The effectiveness of this surface was evaluated by measuring the pull-off force required to separate the coping from the abutment after cementation.

A worst-case approach was applied to define the testing setup. The selection criteria focused on the abutment design, particularly the surface and geometry of the abutment post height, as cement is applied to this region. The minimum post height of 3.5 mm was chosen as the worst-case scenario, since it allows the least amount of cement and therefore represents the most challenging condition for adhesion.

Results demonstrate that the lasered-surface abutments generate higher pull-off force than machined surface abutments, confirming the enhanced cement retention of the new textured surface.

Surface Analysis

The new roughened and structured chimney surface of the Straumann Variobase Abutments XC for Bridge/Bar was analyzed using SEM–EDX. Images demonstrate that the laser-texturized chimney exhibit altered surface topography compared to the machined surface, while retaining an equivalent elemental composition consistent with Ti-6Al-7Nb material.

Conclusion

The conclusion drawn from the nonclinical tests submitted in this premarket notification demonstrates that the Straumann Variobase Abutments XC for Bridge/Bar are substantially equivalent to the primary predicate device.