November 11, 2024

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

Re: K241575
Trade/Device Name: Straumann® Anatomic Healing Abutments XC (AHA)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 24, 2024
Received: October 25, 2024

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241575

Device Name

Straumann® Anatomic Healing Abutments XC (AHA)

Indications for Use *(Describe)*

Straumann® Anatomic Healing Abutments are indicated to be placed in partially edentulous patients after implant placement. The healing components protect the inner configuration of the implant and form, maintain and stabilize the soft tissue during the healing process. Healing components have a maximum duration of usage of 180 days.

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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Traditional 510(k) Submission

Straumann Anatomic Healing Abutments XC (AHA)

K241575

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 Basel BS CH-4002 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:	Laura Bleyendaal Sr. RA Specialist Straumann USA, LLC Phone number: +1 978 747-2768
Date of Submission:	November 5, 2024

Name of the Device

Trade Names:	Straumann Anatomic Healing Abutments XC (AHA)
Common Name:	Abutment, Implant, Dental, Endosseous
Classification Name:	Endosseous dental implant abutment
Regulation Number:	§872.3630
Device Classification:	II

Traditional 510(k) Submission

Straumann Anatomic Healing Abutments XC (AHA)

K241575

Product Code(s): NHA

Classification Panel: Dental

Predicate Device(s)

Primary Predicate:

- Straumann Healing Abutments (K130808)

Reference Devices:

- BellaTek Encode Emergence Healing Abutment (K212730)
- Protective caps of the Straumann Magellan Abutment System (K133421)
- Straumann BLX Basal Screws (K173961)
- MRI Compatibility for Existing Straumann Dental Implant Systems (K190662)

Device Description

The Straumann Anatomic Healing Abutments XC (referred to as the AHAs) are intended for use with the Straumann Dental Implant System (SDIS). The healing components protect the inner configuration of the implant and form, maintain, and stabilize the soft tissue during the osseointegration phase of Straumann endosseous dental implants to be rehabilitated using the delayed loading technique. The AHA are to be used during the implant placement surgery or in the reopening surgery (second surgical phase) and are for temporary use up to 180 days. The AHAs are to be placed out of occlusion. The healing abutments do not support a prosthetic restoration.

The AHAs are composed of two united parts: a body that allows for customization and includes a through hole for fixation screw access, and a basal screw a basal screw that cannot be altered. The Anatomic Healing Abutments are intended to be customized using only hand milling instruments manually controlled by dental professionals. To protect the consistent emergence profile for final abutment, a maximum 3mm height can be modified down to the occlusal surface. To preserve the scanning function of AHA, a

4.7mm circular area around the central axis of the screw channel cannot be modified. Figure 1 depicts, in green, the customizable areas on an AHA. The body is milled from polyetheretherketone (PEEK Classix). The basal screws are existing basal screws manufactured from Titanium-Aluminum-Niobium (TAN) alloy previously cleared as part of the Straumann BLX system in K173961.

Figure 1. Representative image of an AHA connected to a BLX implant. The green area may be customized whereas the red area is not to be customized.

The AHA are designed for connection to BLC and BLX implants of the Straumann Dental Implant System (K173961, K181703, K191256, K210855, K212533, K230108, and K234049). The AHA are available in diameters of Ø3.8 mm, 4.5mm, 5.5mm, and 6.5mm. They are available in 4 shapes designed according to specific areas of the dentition including S, S1, M, and XL, however, they are not limited to use exclusively in these positions. The AHA are offered in regular base (RB) and wide base (WB) configurations consistent with the Straumann BLX and BLC prosthetic platform offerings.

The AHAs may also be used in intraoral scanning procedures of single-unit restorations to represent the position, axis, and orientation of the dental implant placed in the patient's jaw relative to the surrounding dentition. A scanbody feature extends from the

occlusal surface of the AHA.

Intended Use

Straumann sterile healing components are intended for use with implants of the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.

Indications for Use

Straumann Anatomic Healing Abutments are indicated to be placed in partially edentulous patients after implant placement. The healing components protect the inner configuration of the implant and form, maintain and stabilize the soft tissue during the healing process. Healing components have a maximum duration of usage of 180 days.

Summary of Similarities and Differences in Technological Characteristics and Intended Use

The proposed indications for use for the subject AHA are the consistent with the indications for use for the currently marketed Straumann Healing Abutments. Both devices are intended as healing abutments for use with a Straumann dental implant to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. The duration of usage in both statements is identified as a maximum of 180 days stated in another format as up to six months (6 months times approximately 30 days per month results in 180 days). Table 1 includes the exact indications for use statements.

Table 1 Comparison of the subject, primary predicate, and reference devices' indications for use

	Subject Device Straumann Anatomic Healing Abutments (AHA)	**Primary Predicate Straumann Healing Abutments Institute Straumann AG K130808**	**Reference Device BellaTek Encode Emergence Healing Abutment Biomet 3i LLC K212730**	**Reference Device Straumann BLX Basal Screws Institute Straumann AG K173961**	**Reference Device Protective caps of Straumann Magellan Abutment System Institute Straumann AG K133421**
Indications for Use Statement	Intended use Straumann sterile healing components are intended for use with implants of the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Indications for use Straumann Anatomic Healing Abutments are indicated to be placed in partially edentulous patients after implant	Closure screws, healing caps, and healing abutments, are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Customizable healing abutments made of PEEK are for use up to six months.	The BellaTek Encode Emergence Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for acceptance of a final abutment and restoration.[1]	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	The Straumann Magellan abutments are indicated to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns, bridges and bars. The final processed devices have the purpose of restoring chewing function. Magellan abutments are indicated for screw-retained restorations. *The protective caps are placed on abutments to protect*

	Subject Device Straumann Anatomic Healing Abutments (AHA)	**Primary Predicate Straumann Healing Abutments Institute Straumann AG K130808**	**Reference Device BellaTek Encode Emergence Healing Abutment Biomet 3i LLC K212730**	**Reference Device Straumann BLX Basal Screws Institute Straumann AG K173961**	**Reference Device Protective caps of Straumann Magellan Abutment System Institute Straumann AG K133421**
	placement. The healing components protect the inner configuration of the implant and form, maintain, and stabilize the soft tissue during the healing process. Healing components have a maximum duration of usage of 180 days.			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.	*the outer configuration of the abutment and maintain, stabilize and contour the soft tissue during the healing process.*
FDA Product Code	NHA	NHA	NHA	NHA	NHA

The technological characteristics of the subject AHA are consistent with those of the primary predicate and reference devices. Each device features a two-piece screw retained design. Like the previously cleared Straumann healing abutments customizable, the subject AHA may be customized and is composed of a PEEK abutment with a titanium-aluminum niobium (TAN) alloy basal screw that is supplied sterile by gamma radiation for single use. Like the previously

cleared Bellatek Encode Emergence Healing Abutments, the subject AHA can be scanned using an intra oral scanner and features markings that can be visualized in STL files. A detailed comparison of the subject, predicate, and reference devices is included in Table 2.

Table 2 Comparison of the design and technological characteristics of the subject, predicate, and reference devices

	Subject Device Straumann Anatomic Healing Abutments XC (AHA)	**Primary Predicate Straumann Healing Abutments Customizable Institute Straumann AG K130808**	**Reference Device BellaTek Encode Emergence Healing Abutment K212730 Biomet 3i LLC**	**Reference Device Straumann BLX Basal Screws Institute Straumann AG K173961**	**Reference Device Protective caps of Straumann Magellan Abutment System K133421**	**Equivalence Discussion**
Abutment Design	Screw retained	Screw retained	Screw retained[1]	Not applicable	Screw retained	Equivalent
Abutment Shape	Various anatomical shapes intended for different tooth locations	Conical	Conical	Not applicable	Cylindrical protective caps	Numerous shapes of healing abutments are available. The physician chooses the appropriately sized healing abutment based on his treatment plan. Many healing abutments can be further modified chairside by the physician to fit the patient's interocclusal space. No new questions of safety or effectiveness are raised with anatomical shaped healing abutments.
Body (Ø in mm)	3.8, 4.5, 5.5, 6.5	5, 7	TSV abutments 3.5, 4.5, 5.7 Eztetic abutments 2.9 Certain abutments 3.4, 4.1, 5.0 and 6.0[1]	Not applicable	3.5, 4.6	Body Ø is driven by the associated implant and prosthetic system. Different implant systems have different prosthetic platforms. No new questions of safety or effectiveness are raised.
Abutment Length*	Ø3.8mm, Ø4.5mm: 6.2mm and 7.2mm Ø5.5mm, Ø6.5mm: 6.4mm and 7.4mm	Ø5mm: 7.6mm Ø7mm: 8mm	Not specified (abutment height 3, 5, 7mm[1])	Not applicable	Not applicable as placed on the Magellan abutment. Lengths 5, 6, 8mm (from abutment)	Equivalent; the lengths of the proposed AHA are within the range of those of the previously cleared Straumann Healing Abutments customizable (K130808).
Intraoral scanning identification	Dots can be visualized in STL files	No	Encode coding scheme (machined markings) can be visualized in STL files[1]	No	No	Equivalent; the AHA intraoral scanning identification dots are equivalent to the encode coding machined markings on the Bellatek Encode Emergence healing abutments (K212730).
Body Material	Polyetheretherketone (PEEK) Classix ASTM F2026	PEEK ASTM F2026	Titanium-aluminum-vanadium alloy (TAV) ASTM F136 anodized[1]	Not applicable	PEEK Classix ASTM F2026	Equivalent; The AHA is machined from the same material PEEK Classix, as the protective caps of the Straumann Magellan Abutment System (K133421). The two devices fall in the same contact category.
Screw Material	Titanium-aluminum-niobium alloy (TAN)	TAN ISO 5832-11 anodized	TAV ASTM F136[1]	TAN ISO 5832-11 anodized	TAN ISO 5832-11	Same; the basal screw assembled with the AHA is the same basal screw previously cleared in

[1] BellaTek Encode Emergence Healing Abutments 510(k) Summary K212730 accessed at: K212730.pdf (fda.gov).

	Subject Device Straumann Anatomic Healing Abutments XC (AHA)	**Primary Predicate Straumann Healing Abutments Customizable Institute Straumann AG K130808**	**Reference Device BellaTek Encode Emergence Healing Abutment K212730 Biomet 3i LLC**	**Reference Device Straumann BLX Basal Screws Institute Straumann AG K173961**	**Reference Device Protective caps of Straumann Magellan Abutment System K133421**	**Equivalence Discussion**
	ISO 5832-11 anodized					K173961.
Implant Interface	Straumann TorcFit (with conical fitting)	Straumann Regular Crossfit (RC) and Narrow Crossfit (NC) (with conical fitting)	TSV abutments: Zimmer Dental TSV Dental Implant System Eztetic Abutments: Zimmer Dental Eztetic Dental Implant System Certain Abutments: Biomet 3i Certain (Internal Hex) Dental Implant System[1]	Straumann TorcFit (with conical fitting)	Interfaces with abutment	Equivalent; each device is designed to mate with an interface featured in a previously cleared implant or abutment. More specifically, the AHA mates with the Straumann TorcFit connection which is present on the currently marketed Straumann dental implants including the BLX (K17396, K181703, K191256) and BLC (K230108, K234049).
Customization	Customizable	Customizable	Not specified	Not applicable	Customizable	Equivalent; the AHA is manufactured from PEEK and customizable like the Straumann healing abutments customizable (K130808) and the protective caps of the Straumann Magellan Abutment System (K133421).
Sterility/Sterilization	Sterile by gamma radiation End user steam sterilized if customized	Sterile by gamma radiation End user steam sterilized if customized	Sterile by gamma radiation[1]	Non-sterile, end user steam sterilized	Non-sterile, end user steam sterilized	Equivalent; The AHA is supplied sterile and customizable like the previously cleared Straumann healing abutments customizable (K130808).
Packaging	Abutment assembled with basal screw Polyethylene terephthalate glycol (PETG) blister and lid with a Tyvek lid	Abutment assembled with basal screw PETG blister and lid with a Tyvek lid	Blister tray with Tyvek Lid[1]	They are provided along with the abutments but they are also provided as standalone screws. Polyethylene terephthalate glycol-modified (PETGAG) blister tray and an Ovantex sealing lid	Four protective caps each assembled with basal screw PETGAG blister tray and an Ovantex sealing lid	Equivalent; The AHA is packaged in the same packaging as the previously cleared Straumann healing abutments (K130808).
Usage	Single-use, for up to	Single-use, for up to 6	Single-use[1]	Single-use	Single-use, for use up to 6	Equivalent

	Subject Device Straumann Anatomic Healing Abutments XC (AHA)	Primary Predicate Straumann Healing Abutments Customizable Institute Straumann AG K130808	Reference Device BellaTek Encode Emergence Healing Abutment K212730 Biomet 3i LLC	Reference Device Straumann BLX Basal Screws Institute Straumann AG K173961	Reference Device Protective caps of Straumann Magellan Abutment System K133421	Equivalence Discussion
	180 days	months			months	

Performance Testing

Sterilization Validation and Shelf Life

The subject devices will be gamma irradiated, like the predicate devices in K130808. The AHA have been assessed for their relative challenge to the sterilization process by comparison to similar devices previously validated to a sterility assurance level (SAL) of 10^{-6}, utilizing VDmax25 in accordance with ISO 11137-1:2006. The standard dose of radiation used for routine irradiation sterilization is 25 kilogray. This dose has been validated in accordance with ISO 11137-1: 2006, utilizing VDmax25 in accordance with ISO 11137-2: 2013, to achieve a sterility assurance level of 10^{-6}.

If the AHA is customized, the device must be steam sterilized prior to intra-oral use. A validation of the labeled steam sterilization cycle using the half cycle validation approach outlined in ANSI/AAMI/ISO 17665-1: 2006/(R)2013, Annex D was performed with a subject device. All test method acceptance criteria were met.

The subject AHAs are labeled with a 5-year shelf-life like the previously cleared Straumann healing abutments (K130808). The packaging materials, configuration, and sterilization method for the AHA are the same as the Straumann healing abutments. Also, the subject AHA do not represent a new worst case in terms of dimension and weight, therefore, the packaging stability study for the Straumann healing abutments is adopted to support the subject AHA.

The subject devices are implants and will not be marketed as non-pyrogenic. The method used to make the determination that the devices meet pyrogen limit specifications is the *Limulus* amebocyte lysate (LAL) test. The testing limit is 20 endotoxin units (EU)/device. The testing limit is consistent with the recommendation identified in the FDA Guidance Submission and review of sterility information in premarket notification (510(k)) submissions for devices labeled as sterile.

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, (June 16, 2016). The subject AHA devices are manufactured from PEEK Classix conforming to ASTM F2026. The AHA share the same nature of body contact, contact duration, device material and manufacturing process as the reference protective caps of the Straumann Magellan Abutment System (K133421). Unlike the reference protective caps, the subject AHAs will be sterile packaged, and gamma irradiated. Cytotoxicity and chemical extraction tests were performed. No cytotoxic reaction was detected. No extractable substances were detected in the chemical analysis above the analytical evaluation threshold (AET).
The basal screws of the subject AHA are manufactured from Titanium-aluminum-niobium alloy (TAN) conforming to ISO 5832-11. The basal screws of the subject AHA share the same nature of body contact, contact duration, material formulation, and sterilization methods as the basal screws of the primary predicate Straumann healing abutments customizable (K130808) and therefore, no new testing has been performed on these devices.

Electromagnetic Compatibility

No new materials or worst-case constructs were introduced compared to the Straumann portfolio MR tested in accordance with FDA’s guidance testing and labeling medical devices for safety in the magnetic resonance (MR) environment and cleared under K190662.

Performance Testing – Bench

The physician will insert the AHA during the implant placement surgery or in the reopening surgery (second surgical phase) and remove the AHA upon placement of a final abutment and restoration. Therefore, torque testing was performed to demonstrate the AHA withstands repeated insertion and removal torques without damage.

Software Testing

A scan verification test and software integration were performed to demonstrate the subject AHAs can be scanned with an intraoral scanner and are suitable to work with CARES Visual software.

Conclusion

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