January 4, 2024

Anthogyr
% Jennifer Jackson
Sr. Dir, Regulatory & Quality NAM
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01801

Re: K231072
Trade/Device Name: Anthogyr FlexiBase® titanium bases for Axiom® BL
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 5, 2023
Received: December 5, 2023

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.

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)*
K231072

Device Name
Anthogyr FlexiBase® titanium bases for Axiom® BL

Indications for Use *(Describe)*
Anthogyr FlexiBase® titanium bases for Axiom® BL are indicated for use as a support for single-unit customized prosthetic restorations. All digitally designed copings and / or crowns for use with the Anthogyr Flexibase® titanium bases for Axiom® BL are intended to be sent to Straumann for manufacturing by a validated milling center (Straumann CARES System).

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

K231072 - Anthogyr FlexiBase® titanium bases for Axiom® BL

510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC (on behalf of Anthogyr) 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: Anthogyr 2 237 Avenue André Lasquin 74700 Sallanches, France
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:	Estelle SALLE Regulatory Affairs Project Manager Anthogyr Phone number: +33 (0)4 50 58 02 37
Date of Submission:	January 4, 2024

Name of the Device

Trade Names:	Anthogyr FlexiBase® titanium bases for Axiom® BL
Common Name:	Endosseous dental implant abutment (21 CFR 872.3630)
Classification Name:	Endosseous dental implant abutment (21 CFR 872.3630)
Regulation Number:	§872.3630
Device Classification:	II
Product Code(s):	NHA
Classification Panel:	Dental

Predicate Device(s)

Primary Predicate:

- *K150203 – Medentika CAD/CAM Abutments*

Reference Devices:

- *K222836 – Straumann® Variobase® Abutments and Straumann® n!ce® Zirconia Discs*
- *K190082 – Straumann BLX Variobase Abutment*
- *K173961 – Straumann BLX Implant System*
- *K170354 – Straumann® Variobase® Abutments*

Compatible Dental Implants:

- *K161177 – Axiom PX*
- *K131066 – Axiom Reg*
- *K101913 – Anthofit OI, Anthofit HE, Ossfit, and Axiom*

Device Description

Anthogyr FlexiBase® titanium bases for Axiom® BL

Anthogyr FlexiBase® titanium bases for Axiom® BL are intended to be placed into Anthogyr dental implants to provide support for single-unit restorations. The second component of the two-piece abutment (coping or crown) must be cemented onto the titanium component of the FlexiBase® abutment to constitute the final two-piece abutment design, which is then screwed onto the implant.

The bottom portion of the FlexiBase® are made from Titanium alloy. They are provided in several dimensions, there is one chimney height, and two platform diameters of 4.0 mm and 5.0 mm, and for each of the platform diameters there are three gingival heights of 1.5 mm, 2.5 mm and 3.5 mm.

Anthogyr FlexiBase® titanium bases for Axiom® BL are very similar to the primary predicate device Medentika TiBase CAD/CAM Abutments cleared in K150203.

The FlexiBase® are fixed in the implant by means of a prosthetic screw which is manufactured in titanium alloy and DLC coated identical to K161177.

The FlexiBase® abutments are two-piece abutments used as a base when fabricating a CAD/CAM customized restoration. The design and milling of the customized restoration must be made using the Straumann CARES® Visual software.

The FlexiBase® is a two-piece abutment ultimately composed by three components:

- FlexiBase® abutment titanium component
- Top-half component (coping and/or crown)
- Prosthetic screw

The FlexiBase® abutments will be marketed:

- through a validated Straumann Centralized milling center, in this case all digitally designed copings and/or crowns are intended to be manufactured at a validated Straumann milling center (Straumann CARES® System).

Prosthetic Restoration Design and Materials

The following is an overview of the possible coping materials:

- n!ce CoCr
- n!ce Zr LT
- n!ce Zr HT
- n!ce Zr XT
- n!ce glass ceramic
- n!ce PMMA (temporary)

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

Anthogyr prosthetic screw

A prosthetic screw is used to fix abutments to dental implants. The screw is provided with the abutments and also available standalone (replacement).

The prosthetic screws are manufactured from titanium alloy and are DLC coated identical to K161177.

Intended Use

FlexiBase® titanium bases for Axiom® BL are intended to support screw-retained restorations on Axiom® BL dental implants.

Indications for Use

Anthogyr FlexiBase® titanium bases for Axiom® BL are indicated for use as a support for single-unit customized prosthetic restorations. All digitally designed copings and / or crowns for use with the Anthogyr Flexibase® titanium bases for Axiom® BL are intended to be sent to Straumann for manufacturing by a validated milling center (Straumann CARES System).

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 DEVICE		
	Subject Device – Anthogyr FlexiBase® titanium bases for Axiom® BL	**Medentika CAD/CAM Abutments K150203**	**Straumann BLX Variobase Abutment K190082**	**Straumann BLX Implant System K173961**	**Straumann® Variobase® Abutments K170354**
Indication for use	Anthogyr FlexiBase® titanium bases for Axiom® BL are indicated for use as a support for single-unit customized prosthetic restorations. All digitally designed copings and / or crowns for use with the Anthogyr Flexibase® titanium bases for Axiom® BL are intended to be sent to Straumann for manufacturing by a validated milling center (Straumann CARES System).	Medentika CAD/CAM abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. Abutments are compatible with the following implant systems: • E-Series: Nobel Biocare Replace™ Select 3.5, 4.3, 5.0, 6.0 • F-Series: Nobel Biocare NobelActive™ 3.5, 4.3, 5.0 • H-Series: Biomet 3i Osseotite Certain 3.25, 4.0, 5.0 • I-Series: Biomet 3i Osseotite 3.25, 3.75, 4.0, 5.0 • K-Series: Nobel Biocare Brånemark 3.3, 3.75, 4.0, 5.0 • L-Series: Straumann Bone Level 3.3, 4.1, 4.8 • N-Series: Straumann Standard 3.3, 4.1, 4.8 • R-Series: Zimmer Tapered Screw-Vent 3.3, 3.7, 4.1, 4.7, 6.0 • S-Series: Astra Tech OsseoSpeed 3.5/4.0, 4.5/5.0 • T-Series: Dentsply Friadent Frialit/XiVE 3.4, 3.8, 4.5, 5.5 • Y-Series: Dentsply Friadent Ankylos 3.5, 4.5, 5.5, 7.0 Medentika TiBase is intended for use with the Straumann® CARES® System.	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.
Material	Titanium: 3.7165.1-Ti-6Al-4VELI	Titanium Alloy: Ti-6Al-4V ELI	Ti-6Al-7Nb	Ti-6Al-7Nb	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)
Abutment diameters	Ø4 mm and Ø5 mm	Ø 3.0 – 7.0 mm	Ø 3.8 to 5.5 mm	Ø 3.8, 4.5, and 5.5 mm	Ø 3.8 – 7.0 mm

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE		
	Subject Device – Anthogyr FlexiBase® titanium bases for Axiom® BL	**Medentika CAD/CAM Abutments K150203**	**Straumann BLX Variobase Abutment K190082**	**Straumann BLX Implant System K173961**	**Straumann® Variobase® Abutments K170354**
Titanium component Gingival height(s)*	1.5, 2.5 and 3.5 mm*	-	0.75 – 3.5 mm*	0.75 – 2.5 mm*	-
Titanium component chimney height(s)*	3.5 mm*	4 mm - 5.5 mm*	4 mm and 6 mm*	-	3.5 – 4.5 mm*
Minimum Abutment Post Height above the gingival margin of the final design	4 mm	4 mm	4 mm	4 mm	4 mm
Restoration type	Single-unit	Single or multiple tooth prostheses	Screw-retained single-unit, or Cement-retained single or multi-unit	-	-
Top-half materials	n!ce CoCr n!ce Zr LT n!ce Zr HT n!ce Zr XT n!ce® glass ceramic n!ce PMMA (temporary)	Zirconia	coron® zerion® LT zerion® ML and UTML	IPS e.max CAD Polycon® ae	Coron® Zerion® IPS e.max CAD n!ce Polycon® ae
Abutment angulation	Up to 30°	Up to 30°	Up to 30°	Up to 30°	Up to 30°
Prosthesis attachment	Screw-retained	Cement retained	Cement retained	Screw-retained or cement retained	Screw-retained or cement retained
Cement used in device performance testing	PANAVIA V5 by KURARAY DENTAL, cleared by FDA under K150704	Multilink Hybrid Abutment Cement by Ivoclar (K130436).	Kuraray Panavia V5	Kuraray Panavia V5	-

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE		
	Subject Device – Anthogyr FlexiBase® titanium bases for Axiom® BL	**Medentika CAD/CAM Abutments K150203**	**Straumann BLX Variobase Abutment K190082**	**Straumann BLX Implant System K173961**	**Straumann® Variobase® Abutments K170354**
Cement to fix patient-specific coping according to IFU	PANAVIA V5 by KURARAY DENTAL, cleared by FDA under K150704	Multilink Hybrid Abutment Cement by Ivoclar (K130436).	Kuraray Panavia V5	Kuraray Panavia V5	-
Geometry definition workflow	Straumann CARES system validated centralized milling center under manufacturing control	Straumann CARES system validated centralized milling center under manufacturing control	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 Straumann CARES® Visual, Dental Wings software using the Straumann CARES Visual Plug-In and 3Shape
Manufacturing workflow	Straumann Milling Center	Straumann Milling Center	Straumann Milling Center	Straumann Milling Center	Traditional casting or pressing or Straumann Milling Center
Reusable	No, single-use	No, single-use	No, single-use	No, single-use	No, single-use
Sterility	Non sterile – End user sterilization by autoclave	Non sterile – End user sterilization by autoclave	Non sterile – End user sterilization by autoclave	Non sterile – End user sterilization by autoclave	Non sterile – End user sterilization by autoclave

*This dimension is referring to the stock titanium FlexiBase Component only.

Table 1 – Comparison of subject device versus predicate device (Anthogyr FlexiBase® titanium bases for Axiom® BL uses with Straumann CARES System – Validated centralized milling center)

1.1 Performance Testing

Sterilization Validation and Shelf-life

The subject devices 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 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. Cytotoxicity testing was performed on the subject devices per ISO 10993-5.

The subject devices are equivalent in material 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. MR Conditional labeling is referenced from prior testing/clearance (K180564).

Performance Testing – Bench

Dynamic fatigue testing was 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 ISO 14801 "*Dentistry — Implants — Dynamic loading test for endosseous dental implants*" and demonstrated the subject devices are equivalent to the primary predicate and reference devices. The test was conducted in saline (2 Hz and 37 °C) at 2 million cycles covering permanent restoration of the Anthogyr FlexiBase®

titanium bases for Axiom® BL without failure. Test was conducted in saline (2 Hz and 37 °C at 200,000 cycles covering the temporary restoration of the Anthogyr FlexiBase® titanium bases for Axiom® BL without failure.

Conclusion

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