October 16, 2023

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

Re: K230104
Trade/Device Name: Anthogyr AXIOM® BL X3 implants, Anthogyr Multi-Unit components for AXIOM® BL
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 15, 2023
Received: September 18, 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)*
K230104

Device Name
Anthogyr AXIOM® BL X3 Implants

Indications for Use *(Describe)*

The implant system is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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. Multiple tooth applications may be rigidly splinted.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230104

Device Name
Anthogyr Multi-Unit components for AXIOM® BL

Indications for Use *(Describe)*
Anthogyr Multi-Unit prosthetic components directly or indirectly connected to the endosseous dental implants are indicated for use to provide support for multiple-unit prosthetic reconstructions such as bridges and bars. The final devices have the purpose of restoring chewing function. Temporary components can be used prior to the installation of the final components to maintain, stabilize and shape the soft tissue during the healing phase. The temporary restoration may not be placed into occlusion.

Temporary components have a maximum duration of usage of 180 days.

The OPMUN0-0 abutments are indicated for maxillary lateral and mandibular central/lateral incisors only.

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: Anthogyr 2237 Av. André Lasquin, 74700 Sallanches, France Registration No.: 8020776 Owner/Operator No.: 9005052 Jennifer M. Jackson, MS, RAC Senior Director, Regulatory Affairs and Quality NAM Phone Number: +1 978 747-2509 Fax Number: +1 978 747-0023
Prepared By & Alternate Contact:	Aude GOULET/Estelle SALLE Regulatory Affairs Project Manager Anthogyr Phone number: +33450580237
Date of Submission:	October 12, 2023

Name of the Device

Trade Names:	Anthogyr AXIOM® BL X3 implants and Anthogyr Multi-Unit components for AXIOM® BL
Common Name:	Endosseous dental implant

Traditional 510(k) Submission

Anthogyr AXIOM® BL X3 implants and Anthogyr Multi-Unit components for AXIOM® BL

510(k) Summary - K230104

Classification Name:	Endosseous dental implant
Regulation Number:	21 CFR 872.3640
Device Classification:	II
Product Code(s):	DZE, NHA
Classification Panel:	Dental
Proprietary Name:	Anthogyr AXIOM® BL X3 implants and Anthogyr Multi-Unit components for AXIOM® BL

Predicate Device(s)

Primary Predicate:

- K203309 – *NUVO CF Implant System*

Reference Devices:

- *K161177* – AXIOM® PX
- *K173961 – Straumann BLX Implant System*
- *K131066 – Axiom® REG*
- *K101913 – ANTHOGYR DENTAL IMPLANT SYSTEMS : AXIOM*
- *K191123 – Medentika Multi-unit Abutments*
- *K192401 – Straumann® Screw-Retained Abutments*
- *K133421 – Straumann® Magellan Abutment System*
- *K220251 – Neodent Implant System – GM Narrow Implant System*
- *K033922 - Straumann® Modification to ITI Dental Implant System*

Device Description

Subject implants

The Anthogyr AXIOM® BL X3 implants are fully tapered dental bone level implants with external diameters of Ø3.4 mm, Ø4.0 mm, Ø4.6 mm, Ø5.2 mm, Ø5.8 mm and Ø6.4 mm and lengths of 6.5 mm, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, and 18 mm. The implants are manufactured

from the Ti 6Al-4V ELI titanium-aluminum-vanadium alloy material and are finished with BCP (Biphasic Calcium Phosphates) surface treatment. The abutment connection is identified as single conical connection.

Subject prosthetic components

Anthogyr Multi-Unit abutments for AXIOM® BL

The proposed Anthogyr Multi-Unit abutments for AXIOM® BL are dental abutments, which are intended to be screwed onto dental implants to provide support for prosthetic superstructures. Multi-Unit abutments can be used in combination with screw retrained multi-unit dental prosthetics, e.g., bars and bridges. Anthogyr Multi-Unit abutments for AXIOM® BL are very similar to the reference device Medentika Multi-Unit Abutments cleared in K191123.

Anthogyr Multi-Unit abutments for AXIOM® BL include straight and angled (18° and 30°) abutments, prosthetic screw and abutment carrier pin.

Anthogyr Multi-Unit abutments are available as one-piece straight abutments, which have an integrated thread and can be screwed directly into the AXIOM® Bone Level implants, or as two-parts angled abutments, which can be screwed onto the AXIOM® Bone Level implant with the corresponding M1.6 screw.

Anthogyr Multi-Unit abutments for AXIOM® BL exist in two model types:

- Straight Multi-Unit abutments with various gingival heights and two platform diameters (Ø 4.0 and Ø 4.8 mm)
- Angulated Multi-Unit abutments with various gingival heights and angulations.

Anthogyr Multi-Unit protective caps

Anthogyr Multi-Unit protective caps are placed to the Multi-Unit abutments and are intended to be used to protect the abutment and maintain, stabilize and form the soft tissue during the healing phase.

Anthogyr Multi-Unit temporary copings

Anthogyr Multi-Unit temporary copings are compatible with the Multi-Unit abutments and are used for temporary restorations. The copings are placed on the Multi-Unit abutments to support temporary prosthetic superstructures. Temporary copings 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 not be placed into occlusion.
The Multi-Unit temporary copings can be adjusted by the dentist or dental technician to fit the oral situation and are fixed to a compatible Multi-Unit abutment by a M1.4 screw.

Anthogyr Flexibase for Multi-Unit abutments

Anthogyr Flexibase for Multi-Unit abutments are compatible with the Multi-Unit abutments and are used for multiple-unit definitive restorations. The Flexibase are placed on Multi-Unit abutments to support definitive prosthetic superstructures. They are fixed to a compatible Multi-Unit abutment by a M1.4 screw.

Intended Use

Subject implants

Anthogyr dental implants are suitable for endosteal implantation in the maxilla or mandible and for the functional and esthetic oral rehabilitation of patients with missing teeth.

Subject prosthetic components

Anthogyr Multi-Unit abutments are intended to be placed into AXIOM® BL implants to provide support for multi-unit prosthetic reconstructions such as bridges and bars. Copings are fixed to the Multi-Unit abutments in order to provide support for prosthetic reconstructions such as bridges and bars.

Indications for Use

Subject implants

The implant system is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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. Multiple tooth applications may be rigidly splinted.

Subject prosthetic components

Anthogyr Multi-Unit prosthetic components directly or indirectly connected to the endosseous dental implants are indicated for use to provide support for multiple-unit prosthetic reconstructions such as bridges and bars. The final devices have the purpose of restoring chewing function. Temporary components can be used prior to the installation of the final components to maintain, stabilize and shape the soft tissue during the healing phase. The temporary restoration may not be placed into occlusion.

Temporary components have a maximum duration of usage of 180 days.

The OPMUN0-0 abutments are indicated for maxillary lateral and mandibular central/lateral incisors only.

Technological Characteristics Comparison Tables

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

Table 1 - Technological Characteristic Comparison Table (Anthogyr AXIOM BL X3 Implants)

FEATURES	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES				
	K230104	K203309	*K161177*	*K173961*	*K131066*	K101913	K033922
	Anthogyr AXIOM® BL X3 implants	NUVO CF Implant System	AXIOM® PX	Straumann BLX Implant System	Axiom® REG	Anthogyr Dental Implant Systems: AXIOM	Straumann® Modification to ITI Dental Implant System
Indications for Use	The implant system is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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. Multiple tooth applications may be rigidly splinted.	The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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. Multiple tooth applications may be rigidly splinted.	Anthogyr dental implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for stabilization of removable prostheses or fixation of single tooth restorations or partial dentures. Anthogyr dental systems are indicated for one-stage or two-stage surgery.It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading.	Straumann® BLX Implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. BLX Implants can be placed with immediate function on single-tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding abutment components.	Anthogyr AXIOM® REG implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for stabilization of removable prostheses or fixation of single tooth restorations or partial dentures. The Axiom dental system is indicated for one-stage or two-stage surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading. Prefabricated components are intended for use as accessories to dental implants to support implant-supported restorations.	Both Dental Implant Systems are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.	ITI implants are intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients. ITI Dental Implants are for single-stage or two-stage surgery. ITI Dental Implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used.

FEATURES	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES				
	K230104	K203309	*K161177*	*K173961*	*K131066*	K101913	K033922
	Anthogyr AXIOM® BL X3 implants	NUVO CF Implant System	AXIOM® PX	Straumann BLX Implant System	Axiom® REG	Anthogyr Dental Implant Systems: AXIOM	Straumann® Modification to ITI Dental Implant System
Implant type	Bone Level	Bone Level	Bone Level	Bone Level	Bone Level	Bone Level	Tissue Level
Implant to Abutment interface	2,7 mm diameter conical Morse taper connection with tri-lobe	Internal Hex	2,7 mm diameter conical Morse taper connection with tri-lobe	BLX (with conical fitting)	2,7 mm diameter conical Morse taper connection with tri-lobe	2,7 mm diameter conical Morse taper connection with tri-lobe	Straumann® synOcta® connection
Implant Diameter	Ø 3.4 mm, 4.0 mm, 4.6 mm, 5.2 mm, 5.8mm and 6.4 mm	Ø 3.5 mm, 3.75 mm, 4.0, 4.3 mm and 5.0 mm	Ø 3.4 mm, 4.0 mm, 4.6 mm, and 5.2 mm	Ø 4.5 mm, 5.5 mm, 6.5 mm	Ø 3.4 mm and 4.0 mm	Ø 3.4 mm, 4.0 mm, 4.6 mm and 5.2 mm	Ø 3.3mm Ø 4.1mm Ø 4.8mm
Implant Length	Ø 3.4 mm : 8, 10, 12, 14, 16 and 18 mm 4.0 mm : 6.5, 8, 10, 12, 14, 16 and 18 mm 4.6 mm : 6.5, 8, 10, 12 and 14 mm 5.2 mm : 6.5, 8, 10 and 12 mm 5.8mm : 6.5, 8, 10 and 12 mm 6.4 mm : 6.5, 8, 10,12 mm	3.5 mm: 8, 10, 11.5, 13, 16 & 18 mm 3.75 mm: 8, 10, 11.5, 13, 16 & 18 mm 4.0 mm: 7, 8, 10, 11.5, 13, 16 & 18 mm 4.3 mm: 7, 8, 10, 11.5, 13, 16 & 18 mm 5.0 mm: 7, 8, 10, 11.5, 13 & 16 mm	3.4 mm: 8, 10, 12, 14, 16 and 18 mm 4.0 mm : 8, 10, 12, 14, 16 and 18 mm 4.6 mm : 6.5, 8, 10, 12 and 14 mm 5.2 mm : 6.5, 8, 10, 12 mm	Ø 4.5 mm : 6, 8, 10, 12, 14, 16 and 18 mm Ø 5.5 mm : 6, 8, 10, and 12mm Ø 6.5 mm : 6, 8, 10, and 12mm	Ø 3.4 mm : 16 and 18 mm Ø 4.0 mm: 16 and 18 mm	Ø 3.4 mm : 8, 10, 12 and 14 mm Ø 4.0 mm : 6, 8, 10, 12 and 14 mm Ø 4.6 mm : 6, 8, 10, 12 and 14 mm Ø 5.2 mm : 6, 8, 10, 12 and 14 mm	Ø 3.3mm : 8, 10, 12 and 14 mm Ø 4.1mm : 6, 8, 10, 12 and 14 mm Ø 4.8mm : 6, 8, 10, 12 and 14 mm
Thread Design	Tapered body	Apically Tapered, Dual Helix	Tapered body	Tapered body	Tapered body	Tapered body	Tapered body
Surface finish	Sand blasted and acid etched (BCP)	Sand blasted and acid etched (Neoporos)	Sand blasted and acid etched (BCP)	Hydrophilic SLActive®	Sand blasted and acid etched (BCP)	Sand blasted and acid etched (BCP)	SLA® – that is large-grit sandblasted and acid-etched
Material	Titanium-6Aluminum-4Vanadium ELI (grade 23)	Commercially Pure Titanium (Grade 4)	Titanium-6Aluminum-4Vanadium ELI (grade 23)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-6Aluminum-4Vanadium ELI (grade 23)	Titanium-6Aluminum-4Vanadium ELI (grade 23)	Titanium (Grade4)
Single Use	Yes	Yes	Yes	Yes	Yes	Yes	Yes

FEATURES	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES				
	K230104	**K203309**	***K161177***	***K173961***	***K131066***	**K101913**	**K033922**
	Anthogyr AXIOM® BL X3 implants	**NUVO CF Implant System**	**AXIOM® PX**	**Straumann BLX Implant System**	**Axiom® REG**	**Anthogyr Dental Implant Systems: AXIOM**	**Straumann® Modification to ITI Dental Implant System**
Sterilization Method	Gamma Irradiation to an SAL of $1x10^{-6}$	Gamma Irradiation to an SAL of $1x10^{-6}$	Gamma Irradiation to an SAL of $1x10^{-6}$	Gamma Irradiation to an SAL of $1x10^{-6}$	Gamma Irradiation to an SAL of $1x10^{-6}$	Gamma Irradiation to an SAL of $1x10^{-6}$	Gamma Irradiation to an SAL of $1x10^{-6}$

The subject implants have the same indications for use and an equivalent range of lengths as the primary predicate and reference devices, being contemplated within the range of lengths of the predicate devices.

Subject and predicate implants have the similar implant-to-abutment interface. Both present the same surfaces. The subject implants are manufactured of the similar materials and are sterilized using the same sterilization method as the primary predicate devices. Subject and reference predicate devices present the same range of sizes and similar overall design.

Overall, the subject devices are equivalent to the predicate devices and reference devices as follows:

- The indications for use is identical to those of the primary predicate device,
- The implant type is identical to those of the primary predicate and reference devices,
- The implant to abutment interface is identical to those of the reference device K161177, K131066 and K101913,
- The implant diameter is similar to those of the primary predicate and reference devices,
- The implant length is similar to those of the primary predicate and reference devices,
- The thread design is similar to those of the reference devices,
- The surface finish is identical to those of the reference devices K161177, K131066 and K101913,
- The material is identical to those of the reference devices K161177, K131066 and K101913,
- Singe use is identical to those of the primary predicate and reference devices,
- Sterilization method is identical to those of the primary predicate and reference devices.

Overall, the subject devices differ from the predicate and reference devices as follow:

- Implant diameter difference :5.8 mm and 6.4 mm diameters.
- Implant length differences:
  - Ø 4.0 mm with 6.5 length
  - All the lengths for Ø 5.8mm and Ø 6.4
- Thread design difference: The external design with the reduced thread in thickness and height (alternation of machined and non-machined thread top).

Table 2 – Comparison of subject device versus reference device (Anthogyr Multi-Unit abutments for AXIOM® BL)

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES			
	Subject Device – Anthogyr Multi-Unit components for AXIOM®BL K230104	**Medentika Multi-unit Abutments K191123**	**Straumann® Screw-Retained Abutments K192401**	**Straumann® Magellan Screw-Retained Abutment System K133421**	**Neodent Implant System – GM Narrow Implant System K220251**
Intended use	Anthogyr Multi-Unit abutments are intended to be placed into AXIOM® BL implants to provide support for multi-unit prosthetic reconstructions such as bridges and bars. Copings are fixed to the Multi-Unit abutments in order to provide support for prosthetic reconstructions such as bridges and bars.	The Multi-unit Abutments are directly screwed into the implant and have a universal mounting on the face side for various additional prosthetic parts. The bridge or bar elements are produced to fit to the prosthetic parts by which they are screwed onto the Multi-unit Abutments.	Straumann abutments are intended to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns and bridges. Copings are fixed to abutments in order to provide support for prosthetic reconstructions such as crowns, bridges and bar-retained over-dentures.	Straumann® dental implants and abutments are intended for use in oral implantation to provide a support structure for connected prosthetic devices.	This product is Indicated for crown or bridge screwed restorations on implants installed in maxilla or mandible (NGM micro abutment).

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES			
	Subject Device – Anthogyr Multi-Unit components for AXIOM®BL **K230104**	**Medentika Multi-unit Abutments** **K191123**	**Straumann® Screw-Retained Abutments** **K192401**	**Straumann® Magellan Screw-Retained Abutment System** **K133421**	**Neodent Implant System – GM Narrow Implant System** **K220251**
Indications for use	Anthogyr Multi-Unit prosthetic components directly or indirectly connected to the endosseous dental implants are indicated for use to provide support for multiple-unit prosthetic reconstructions such as bridges and bars. The final devices have the purpose of restoring chewing function. Temporary components can be used prior to the installation of the final components to maintain, stabilize and shape the soft tissue during the healing phase. The temporary restoration may not be placed into occlusion. Temporary components have a maximum duration of usage of 180 days. The OPMUN0-0 abutments are indicated for maxillary lateral and mandibular central/lateral incisors only.	Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient. Multi-unit Abutments are used for the restoration of the following dental implant systems (Implant System / Series / Implant diameter / Platform diameter): Dentsply® Implants - ASTRA TECH OsseoSpeed® / EVSeries / Diameter 3.6, 4.2, 4.8 / Platform 3.6, 4.2, 4.8 Nobel Biocare NobelActive - NobelReplace Conical / F-Series / Diameter 3.5, 4.3, 5.0 / Platform NP 3.5, RP 4.3/5.0 Biomet 3i - Certain / HSeries / Diameter 3.25, 4.0 / Platform 3.4, 4.1 Straumann - Bone Level / L-Series / Diameter 3.3, 4.1, 4.8 / Platform 3.3, 4.1, 4.8 Straumann - Soft Tissue Level / N-Series / Diameter 4.1, 4.8 / Platform 4.8, 6.5 Zimmer Dental Tapered Screw-vent / R-Series / Diameter 3.3, 3.7, 4.1,4.1, 4.7 / Platform 3.5, 4.5	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 are to be placed out of occlusion. Final abutments may be placed into occlusion for implants with sufficient primary stability or for implants that are fully osseointegrated. Temporary Abutments have a maximum duration of usage of 180 days.	Magellan™ abutments are indicated to be placed into dental implants to provide support for prosthetic reconstructions such as crown, bridges and bars. The final processed devices have the purpose of restoring chewing function.	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.

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES			
	Subject Device – Anthogyr Multi-Unit components for AXIOM®BL K230104	**Medentika Multi-unit Abutments K191123**	**Straumann® Screw-Retained Abutments K192401**	**Straumann® Magellan Screw-Retained Abutment System K133421**	**Neodent Implant System – GM Narrow Implant System K220251**
Material	Titanium-6Aluminium-4Vanadium ELI	Ti6Al4V, medical grade 5, conforming ASTM F136	Titanium Alloy (Ti-6Al-7Nb)	Titanium Alloy (Ti6Al7Nb)	Titanium alloy ASTM F136 (Ti6Al4V-ELI,)
Platform diameter	Ø 4.8 mm and Ø 4.0 mm	EV series: 3.6 - 4.8 mm F series: 3.5 - 5.0 mm H series: 3.4 - 4.1 L series: NC 3.3 - RC 4.1 - 4.8 mm N series: RN 4.8 - WN 6.5 mm R series: 3.5 - 4.5 mm	Ø3.5 and 4.6 mm	Ø 3.5 and 4.6 mm	Ø 3. 5 mm
Gingival heights	0.75 mm, 1.5 mm, 2.5 mm, 3.5 mm and 4.5 mm	GH 0.6 to GH 5.5 mm	1.5, 2.5, 3.5, 4.5 and 5.5 mm	1.0, 2.5 and 4.0 mm	0,8; 1.5, 2.5, and 3.5
Angulation	0°, 18° and 30°	Straight, 17°, 30°	0°, 17°, and 30°	0, 17 and 30°	0°
Abutment design	Straight abutments: one-piece, integrated thread Angulated abutments: two-parts, separate screw.	Straight abutments: one-piece, integrated thread Angulated abutments: two-piece, separate screw.	Straight abutments: one-piece, integrated thread Angulated abutments: two-piece, separate screw.	Straight abutments: one-piece, integrated thread Angulated abutments: two-piece, separate screw.	One-piece, integrated thread

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES			
	Subject Device – Anthogyr Multi-Unit components for AXIOM®BL K230104	**Medentika Multi-unit Abutments K191123**	**Straumann® Screw-Retained Abutments K192401**	**Straumann® Magellan Screw-Retained Abutment System K133421**	**Neodent Implant System – GM Narrow Implant System K220251**
Material of Multi-Unit base/coping	Titanium-6Aluminium-4Vanadium ELI	Ti6Al4V, medical grade 5, conforming ASTM F136 Gold Cobalt-Chromium	Titanium Alloy (Ti6Al7Nb) Ceramicor Use the copings cleared in K133421.	Titanium Alloy (Ti6Al7Nb) Ceramicor	-
Restoration type	Multi-unit restorations	Multi-unit restorations	Single and Multi (Straight NC GH 1.0 mm (Ø 3.5 mm and Ø4.6 mm), are indicated for single-crown restorations in central and lateral incisors, and for multiunit restorations in incisors to premolars)	Single-unit and multi-unit restorations	Single-unit and multi-unit restorations
Reusable	No, single use	No, single use	No, single use	No, single use	No, single use
Sterilization method	Delivered sterile by gamma radiation to an SAL 10^{-6}	Delivered sterile by gamma irradiation to an SAL 10^{-6}	Delivered sterile by gamma Irradiation to an SAL 10-6	Delivered non-sterile, end user sterilized	delivered sterile via Ethylene Oxide to an SAL of 10^{-6}.

Table 3 – Comparison of subject device versus reference device (Anthogyr Multi-Unit temporary copings)

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES		
	Subject Device – Anthogyr Multi-Unit components for AXIOM® BL K230104	**Medentika Multi-unit Abutments K191123**	**Straumann® BLX Implant System K173961**	**Straumann® Screw-Retained Abutments K192401**
Indications for use	Anthogyr Multi-Unit prosthetic components directly or indirectly connected to the endosseous dental implants are indicated for use to provide support for multiple-unit prosthetic reconstructions such as bridges and bars. The final devices have the purpose of restoring chewing function. Temporary components can be used prior to the installation of the final components to maintain, stabilize and shape the soft tissue during the healing phase. The temporary restoration may not be placed into occlusion. Temporary components have a maximum duration of usage of 180 days. The OPMUN0-0 abutments are indicated for maxillary lateral and mandibular central/lateral incisors only.	Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient. Multi-unit Abutments are used for the restoration of the following dental implant systems (Implant System / Series / Implant diameter / Platform diameter): Dentsply® Implants - ASTRA TECH OsseoSpeed® / EVSeries / Diameter 3.6, 4.2, 4.8 / Platform 3.6, 4.2, 4.8 Nobel Biocare NobelActive - NobelReplace Conical / F-Series / Diameter 3.5, 4.3, 5.0 / Platform NP 3.5, RP 4.3/5.0 Biomet 3i - Certain / HSeries / Diameter 3.25, 4.0 / Platform 3.4, 4.1 Straumann - Bone Level / L-Series / Diameter 3.3, 4.1, 4.8 / Platform 3.3, 4.1, 4.8 Straumann - Soft Tissue Level / N-Series / Diameter 4.1, 4.8 / Platform 4.8, 6.5 Zimmer Dental Tapered Screw-vent / R-Series / Diameter 3.3, 3.7, 4.1, 4.1, 4.7 / Platform 3.5, 4.5	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. Temporary Abutments have a maximum duration of usage of 180 days.

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES		
	Subject Device – Anthogyr Multi-Unit components for AXIOM® BL K230104	**Medentika Multi-unit Abutments K191123**	**Straumann® BLX Implant System K173961**	**Straumann® Screw-Retained Abutments K192401**
Material	Titanium-6Aluminium-4Vanadium ELI	Ti6Al4V, medical grade 5, conforming ASTM F136	TAN : Ti-6Al-7Nb	Ti-6Al-7Nb (TAN)
Diameter	Ø 4.8 mm and Ø 4.0 mm	Ø 5.25 mm	Ø 3.8, 4.5, 5.5 and 6 mm	Ø3.5 and 4.6 mm
Duration of use	180 days	unlimited	180 days	maximum of 180 days
Restoration	Multi unit restorations	Multi unit restorations	unknown	single crowns and bridges
Surface treatment	Yellow anodization for MUC100	NA	Anodized signal violet	NA
Chimney design	For Straight access Ø 4.8 and Ø 4.0: Wall thickness: 0.9 mm For Angulated access (angulation = 0°):Wall thickness: 0.8 mm For angulated access (10°, 15°, and 25°) Wall thickness: 0.3 mm	Wall thickness: 0.85 mm	Wall thickness: 0.1 mm	For 3.5 NC wall thickness: 0.3 mm For 4.6 NC and RC wall thickness: 0.3 mm

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES		
	Subject Device – Anthogyr Multi-Unit components for AXIOM® BL K230104	**Medentika Multi-unit Abutments K191123**	**Straumann® BLX Implant System K173961**	**Straumann® Screw-Retained Abutments K192401**
Sterilization method	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 – Steam Autoclave

Table 4 – Comparison of subject device versus reference device (Anthogyr Multi-Unit protective caps)

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES	
	Subject Device – Anthogyr Multi-Unit components for AXIOM® BL K230104	**Medentika Multi-unit Abutments K191123**	**Straumann® Magellan Abutment System K133421**
Indications for use	Anthogyr Multi-Unit prosthetic components directly or indirectly connected to the endosseous dental implants are indicated for use to provide support for multiple-unit prosthetic reconstructions such as bridges and bars. The final devices have the purpose of restoring chewing function. Temporary components can be used prior to the installation of the final components to maintain, stabilize and shape the soft tissue during the healing phase. The temporary restoration may not be placed into occlusion. Temporary components have a maximum duration of usage of 180 days. The OPMUN0-0 abutments are indicated for maxillary lateral and mandibular central/lateral incisors only.	Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient. Multi-unit Abutments are used for the restoration of the following denta implant systems (Implant System / Series / Implant diameter / Platform diameter): Dentsply® Implants - ASTRA TECH OsseoSpeed® / EVSeries / Diameter 3.6, 4.2, 4.8 / Platform 3.6, 4.2, 4.8 Nobel Biocare NobelActive - NobelReplace Conical / F-Series / Diameter 3.5, 4.3, 5.0 / Platform NP 3.5, RP 4.3/5.0 Biomet 3i - Certain / HSeries / Diameter 3.25, 4.0 / Platform 3.4, 4.1 Straumann - Bone Level / L-Series / Diameter 3.3, 4.1, 4.8 / Platform 3.3, 4.1, 4.8 Straumann - Soft Tissue Level / N-Series / Diameter 4.1, 4.8 / Platform 4.8, 6.5 Zimmer Dental Tapered Screw-vent / R-Series / Diameter 3.3, 3.7, 4.1,4.1, 4.7 / Platform 3.5, 4.5	Magellan™ abutments are indicated to be placed into dental implants to provide support for prosthetic reconstructions such as crown, bridges and bars. The final processed devices have the purpose of restoring chewing function.
Material	Titanium-6Aluminium-4Vanadium ELI	Titanium Grade 5	polyetheretherketone (PEEK) cap and Ti-6Al-7Nb (TAN) screw
Protective cap diameter	Ø 4.8 mm and Ø 4.0 mm	unknown	3.5 mm (NC) 4.6 mm (NC and RC)

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES	
	Subject Device – Anthogyr Multi-Unit components for AXIOM® BL K230104	**Medentika Multi-unit Abutments K191123**	**Straumann® Magellan Abutment System K133421**
Shape	Columnar design	Columnar design	Columnar design
Duration of use	180 days	180 days	180 days
Protective cap sterilization method	Provided sterile by gamma irradiation	Provided nonsterile, sterilized by end user	Non-Sterile End User – Steam Autoclave

The subject devices are substantially equivalent in design, function, sizes and materials to the predicate devices previously cleared in K191123, K192401, K133421, and K220251.

The data included in this submission demonstrate substantial equivalence to the predicate devices. Any differences in the technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness.

Overall, the subject devices have the following similarities to the predicate device and reference devices:

- The intended use is identical to those of the reference device, K19240,
- The Indications for use are similar to those of the predicate and reference devices,
- The restoration type is identical to those of the K191123,
- Incorporate a basic design similar to those of the predicate and reference devices,
- The material type (titanium) is similar to those of the predicate and reference devices, and
- The sterilization method is identical to those of K191123 and K192401 for devices delivered in a sterile state. The sterilization method is identical to those of the reference devices for devices delivered non-sterile.

Overall, the subject devices differ from the predicate and reference devices as follow:

- OPMUN0-0 Multi-Unit abutment is indicated for multiple-unit restoration only while K220251 is for both single-unit and multiple-unit restorations.
- OPMUN0-0 Multi-Unit abutment is not recommended for placement positions 3, 4, 5, 6, 7, and 8.
- Anthogyr provide temporary coping with angulated screw channel access (10°, 15° and 25°).

Electromagnetic Compatibility and Electrical Safety

There are no significant changes to the materials and dimensions from the currently cleared predicate devices. Therefore, no new issues of electromagnetic compatibility are raised for the subject devices and they can be considered MR Conditional.

The MR Conditional tests were conducted according to FDA's Guidance "Testing and Labeling Medical Devices for Safety in Magnetic Resonance (MR) Environment".

Performance Testing

Dynamic fatigue 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 Anthogyr AXIOM® BL X3 implants and Anthogyr Multi-Unit components for AXIOM® BL are equivalent to the predicate and reference devices.

The subject device materials are identical to the predicate and reference device materials, therefore, no new issues regarding biocompatibility were raised. The subject devices have the equivalent nature of body contact, contact duration, material formulation and sterilization methods compared to the primary and reference predicate devices.

For anodized parts, cytotoxicity tests were conducted to the ISO 10993-5 standard "*Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity*" and demonstrated the non-cytotoxicity potential of the parts.

The sterilization process for the Anthogyr AXIOM® BL X3 implants, Anthogyr Multi-Unit abutments for AXIOM® BL, and Anthogyr Multi-Unit protective caps are provided sterile via gamma irradiation. A Sterility Assurance Level (SAL) of 10^{-6} had been validated according to ISO 11137-1**:** *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices***.**

The sterilization process as recommended in the labeling for Multi-Unit restorations and prosthetic screws was validated according to standards ISO 17664*: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices* and ISO 17665-1: *Sterilization of health care products - Moist heat - Part 1: requirements for the development, validation and routine control of a sterilization process for medical devices.*

The surface area with and without 3mm of bone resorption, bone to implant contact, and pullout strength were compared to a reference device, K033922, and the results were substantially equivalent.

Conclusion

The documentation submitted in this premarket notification demonstrates the Anthogyr Axiom® BL X3 implants and Anthogyr Multi-Unit components for AXIOM® BL are substantially equivalent to the primary predicate and reference devices.