December 22, 2023

Anthogyr
℅ Jennifer Jackson
Senior Director, Regulatory & Quality NAM
The Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01801

Re: K233264
Trade/Device Name: Anthogyr INTEGRAL Guided Surgery Cassettes
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: September 28, 2023
Received: September 29, 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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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)*

K233264

Device Name

Anthogyr INTEGRAL Guided Surgery Cassettes

Indications for Use *(Describe)*

The Anthogyr Cassettes are designed to hold various dental surgical drills and tools in order to organize, steam sterilize, and protect the instruments that are sterilized by healthcare provider. The cassette is to be enclosed in an FDA cleared steam sterilizable pouch. The cassettes are not intended on their own to maintain sterility.

The cycle of sterilization, for Anthogyr INTEGRAL Guided Surgery Cassettes, uses pre-vacuum steam: 132 °C (270º F) during 4 minutes with 30 minutes drying time.

Anthogyr INTEGRAL Guided Surgery Cassettes have been validated for a maximum load of with the associated instrument. The worst-case recommended load is: 886 g.

The device dimension of Anthogyr INTEGRAL Guided Surgery Cassettes is 290x176x62 mm.

The cassettes are not intended to be stacked during sterilization process.

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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5 510(k) Summary - K233264

5.1 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 2237 Av. André Lasquin, 74700 Sallanches, France
Contact Person:	Jennifer M. Jackson, MS Sr Dir, Regulatory & Quality NAM Phone Number: +1 978 747-2509 Fax Number: +1 978 747-0023
Prepared By & Alternate Contact:	Aude GOULET Regulatory Affairs Project Manager Anthogyr Phone number: +33450580237
Date of Submission:	28/09/2023

5.2 Name of the Device

Trade Names:	Anthogyr INTEGRAL Guided Surgery Cassettes
Common Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Classification Name:	Sterilization Wrap
Regulation Number:	21 CFR 880.6850
Device Classification:	II
Product Code(s):	KCT
Classification Panel:	General Hospital
Proprietary Name:	Anthogyr INTEGRAL Guided Surgery Cassettes

5.3 Predicate Device(s)

Primary Predicate:

- *K203753 Straumann Surgical Cassettes*

Product Code(s):	KCT
Device Classification:	II
Classification name	Sterilization Wrap
Regulation Number:	21 CFR 880.6850

5.4 Device Description

Anthogyr cassettes are reusable rigid containers, comprising a case bottom (base), one or more removable inner tray base (tray) and a tray lid (lid). The trays are composed of brackets made of medical grade silicone, namely brackets used to maintain the Anthogyr dental instruments in place during the surgical or prosthetic procedure and during sterilization. The base and trays have markings and/or colors code to indicate either the surgical workflow, or the position of the instruments in the kit. The lid holds all the instruments securely in place during treatment.

To facilitate the surgical procedure and the correct use and positioning of the instruments, the trays have instrument pictograms and/ or color-coded workflows printed on the surface. Surgical instruments of the Anthogyr Dental Implant System intended to be placed in the Anthogyr cassettes are used for bed preparation, placement, maintenance and explanation of the implants from Anthogyr Dental Implant System. These devices are all Class I exempt or already have class II pre-market notification clearance as described in 21 CFR 872.3980 (Endosseous dental implant accessories) and are not subject devices of this submission.

Intended Use

Anthogyr cassettes are intended to organize instruments, and secure instruments during the sterilization phase.

5.5 Indications for Use

The Anthogyr Cassettes are designed to hold various dental surgical drills and tools in order to organize, steam sterilize, and protect the instruments that are sterilized by healthcare provider.

The cassette is to be enclosed in an FDA cleared steam sterilizable pouch. The cassettes are not intended on their own to maintain sterility.

The cycle of sterilization, for Anthogyr INTEGRAL Guided Surgery Cassettes, uses pre-vacuum steam: 132 °C (270º F) during 4 minutes with 30 minutes drying time.

Anthogyr INTEGRAL Guided Surgery Cassettes have been validated for a maximum load of with the associated instrument. The worst-case recommended load is: 886 g.

The device dimension of Anthogyr INTEGRAL Guided Surgery Cassettes is 290x176x62 mm.

The cassettes are not intended to be stacked during sterilization process.

5.6 Technological Characteristics

The subject devices and primary predicate devices as K203753 share the following characteristics:

- Identical indications for use
- Identical Product code
- Identical Design
- Equivalent Material
- Identical Materials compatible with sterilization method
- Identical Perforated
- Identical Reusable
- Identical Sterilization Method
- Identical Cycles
- Identical Parameters
- Identical Sterile Barrier
- Identical Biocompability

The main differences between the primary predicate device (K203753) with the integral guided surgery cassettes subject devices are in the Table 1:

	Dimensions	Max weight loaded
Primary Predicate Device K203753	290mm x 176mm x 60mm	1005g
Integral guided surgery cassettes subject devices	290mm x 176mm x 62mm	886g

Table 1 – Differences between the primary predicate device with the integral guided surgery cassettes subject devices

The technological characteristics of the subject devices are compared to the primary predicate and primary predicate device in the Table 2.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICES	
	K23XXXX	K203753	
	Anthogyr INTEGRAL Guided Surgery Cassettes	Straumann Surgical Cassettes	Equivalence discussion
Indications for Use	The Anthogyr Cassettes are designed to hold various dental surgical drills and tools in order to organize, steam sterilize, and protect the instruments that are sterilized by healthcare provider. The cassette is to be enclosed in an FDA cleared steam sterilizable pouch. The cassettes are not intended on their own to maintain sterility. The cycle of sterilization, for Anthogyr INTEGRAL Guided Surgery Cassettes, uses pre-vacuum steam: 132 °C (270º F) during 4 minutes with 30 minutes drying time. Anthogyr INTEGRAL Guided Surgery Cassettes have been validated for a maximum load of with the associated instrument. The worst-case recommended load is: 886 g. The device dimension of Anthogyr INTEGRAL Guided Surgery Cassettes is 290x176x62 mm. The cassettes are not intended to be stacked during sterilization process.	The instrument kits are designed to hold various dental surgical drills and tools in order to organize, steam sterilize, and protect the instruments that are sterilized by healthcare provider. The cassette is to be enclosed in an FDA cleared steam sterilizable pouch. The cassettes are not intended on their own to maintain sterility The Straumann Cassettes are used to organize, store, sterilize and transport surgical instruments and auxiliaries between and during surgical uses. They are indicated to be used in healthcare facilities by healthcare professionals. The Straumann Cassettes are to be enclosed in FDA cleared sterilization pouches in two layers to maintain the sterility of the enclosed devices using the following sterilization parameters: pre-vacuum steam exposure at 132°C (270º F) for 4 minutes, 30 minutes drying time. The Straumann Cassettes have been validated for a maximum load of 1005 grams for the Surgical Cassettes, 2007 grams for the Osteotome Cassettes, 283 grams for the Bone Block Fixation Cassette and 65 grams for the Screw Container, including cassette and instruments..	**Identical** The subject cassette devices have the same indication of use as the primary predicate.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICES	
	K23XXXX	K203753	
	Anthogyr INTEGRAL Guided Surgery Cassettes	Straumann Surgical Cassettes	Equivalence discussion
Product code	KCT	KCT	**Identical** The subject cassette devices have the same product code as the primary predicate and the reference predicate.
Design	Reusable rigid container, case bottom (base), a removable inner tray base (tray), and tray lid (lid).	Reusable rigid container, case bottom (base), a removable inner tray base (tray), and tray lid (lid).	**Identical** The subject cassettes have the same design as the primary predicate device.
Dimensions	290x176x62 mm	290mm x 76mm x 60mm 290.10mmx174.50mmx53 mm 130mmx118mmx25mm 68.5mmx46.5mmx 22.2mm	**Identical** The subject cassette devices have the same dimensions as the primary predicate.
Materials	Polyphenylsulfone (Radel R-5000) Polyphenylsulfone (Radel R-5100) Medical grade silicone Stainless steel	Polyphenylsulfone (Radel R-5000) Silicone Stainless Steel	**Equivalent** The subject cassettes have equivalent materials as the primary predicate device. Because the difference between the R-5000 et R-5100 is the color.
Materials compatible with sterilization Method	Yes	Yes	**Identical** The subject cassettes have the same materials compatible with sterilization method as the primary predicate device.
Perforated	Yes; allows moist heat (steam) penetration to achieve sterilization	Yes; allows moist heat (steam) penetration to achieve sterilization	**Identical** The subject cassettes have the same perforated as the primary predicate device.
Reusable	Yes, up to 100x	Yes, up to 100x	**Identical** The subject cassettes have the same resusable life as the primary predicate device.
Sterilization Method	Moist heat (steam) to a SAL of 10^{-6}	Moist heat (steam) to a SAL of 10^{-6}	**Identical** The subject cassettes have the same sterilization method as the primary predicate device..

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICES	
	K23XXXX	K203753	
	Anthogyr INTEGRAL Guided Surgery Cassettes	Straumann Surgical Cassettes	Equivalence discussion
Cycles	Pre-Vacuum Steam Sterilization	Fractionated vacuum (pre-vacuum)	**Identical** The subject cassettes have the same cycle as the primary predicate device..
Parameters	Pre-Vacuum: Sterilization temperature: 132º C (270º F). Sterilization time: 4 minutes. Drying time: 30 minutes.	Pre-Vacuum: Sterilization temperature: 132º C (270º F). Sterilization time: 4 minutes. Drying time: 30 minutes.	**Identical** The subject cassette have the parameter of sterilization as the primary predicate device.
Sterile Barrier	Sterilization wrap, FDA-cleared for indicated method and cycles	Sterilization wrap, FDA-cleared for indicated method and cycles	**Identical** The subject cassettes have the same sterile barrier as the primary predicate device.
Biocompatibility	The Biocompatibility assessment was performed per ISO 10993-1 and testing was performed using methods described in ISO 10993-5. The results indicate that the subject devices are non-cytotoxic.	The Biocompatibility assessment was performed per ISO 10993-1 and testing was performed using methods described in ISO 10993-5. The results indicate that the subject devices are non-cytotoxic.	**Identical** The subject cassettes have the same biocompability as the primary predicate device.

Table 2 – Comparison of subject device versus Primary predicate Device

5.7 Non-Clinical Performance data

The performance during multiple reprocessing steps for the Anthogyr INTEGRAL Guided Surgery Cassettes, as recommended in the labeling, was validated according to applicable recommendations in the FDA guidance document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015”.

The non-clinical testing performed with the subject device are listed below:

- Manual cleaning validation
- Automated cleaning validation
- Sterilization validation, including sterilant penetration and drying time
- Life cycle (simulate usage) testing
- Cytotoxicity testing

The worst-case cassettes were tested for performance based on critical impact factors including materials, vent to volume ratio, design complexity, weight of the loaded cassettes or the weight of the empty cassettes. The summary of testing performed is provided in Table 3 for subject devices.

Standard or Test Method	Purpose of the Testing	Acceptance Criteria	Results
Custom	• Test Soil: Blood Soil (BLSO) • Cleaning Method: Manual • Residuals Tested: Hemoglobin and Protein	Visual Inspection: No Visible Soil Hemoglobin Test: <2.2 µg/cm2 Protein Test: <6.4 µg/cm2	Passed
Custom	• Test Soil: Blood Soil (BLSO) • Cleaning Method: Automated • Residuals Tested: Hemoglobin and Protein	Visual Inspection: No Visible Soil Hemoglobin Test: <2.2 µg/cm2 Protein Test: <6.4 µg/cm2	Passed
ISO 17665-1	Sterilization validation, including sterilant penetration and drying time	All Biological Indicators must be incubated for at least 7 days at 55-60°C. All positive controls for SAL testing must show characteristic growth of the indicator organism.	Passed
Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff	Life cycle (simulate usage) testing	The tested samples must withstand 100 cycles of use (cleaning, sterilization, and functional tests) without compromising their functionalities	Passed
ISO 10993-5 (Cytotoxicity)	Cytotoxicity testing	Less than 30% cell proliferation inhibition	Passed

Table 3 – Performance testing summary (Anthogyr INTEGRAL Guided Surgery Cassettes)

5.8 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, Anthogyr INTEGRAL Guided Surgery Cassettes, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K203753.