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

July 11, 2023

Re: K230680
Trade/Device Name: Anthogyr Surgical Cassettes
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: June 9, 2023
Received: June 9, 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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2023.07.11 14:44:58 -04'00'

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K230680

Device Name
Anthogyr Surgical Cassettes

Indications for Use *(Describe)*
The Anthogyr Surgical 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 is:
INMODOPS3, INMODOPS3L, INMODOPP3, INMODIGM, INMODOPS3V, INMODOPS3LV, INMODOPP3V, INMODIGMV: Pre-vacuum steam: 132 °C (270º F) during 4 minutes with 20 minutes drying time
The Anthogyr Surgical Cassettes have been validated for a maximum load of with the associated instruments:
The worst-case recommended load is 412g.
The device dimensions are listed below for Anthogyr Surgical Cassettes:
- INMODOPS3, INMODOPS3V, INMODOPS3L, INMODOPS3LV, INMODOPP3, INMODOPP3V: 130x155x47 mm
- INMODIGM, INMODIGMV: 76x155x47 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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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 2237 Av. André Lasquin, 74700 Sallanches, France
Contact Person:	Jennifer M. Jackson, MS, RAC Senior Director, Regulatory Affairs & 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:	July 10, 2023

Name of the Device

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

Predicate Device(s)

Primary Predicate:

- K160730 – Instrument Kits (Anthogyr)

Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulation Number:	21 CFR 880.6850
Device Classification:	II
Product Code(s):	KCT

Reference Devices:

- K203618 – Neodent EasyGuide Kit Cases (JJGC Indústria e Comércio de Materiais Dentários SA)

Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulation Number:	21 CFR 880.6850
Device Classification:	II
Product Code(s):	KCT

Device Description

Anthogyr Surgical 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 and prosthetic instruments of the Anthogyr Dental Implant System intended to be placed in the Anthogyr Surgical 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.

Indications for Use

The Anthogyr Surgical 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 is:

INMODOPS3, INMODOPS3L, INMODOPP3, INMODIGM, INMODOPS3V, INMODOPS3LV, INMODOPP3V, INMODIGMV: Pre-vacuum steam: 132 °C (270º F) during 4 minutes with 20 minutes drying time

The Anthogyr Surgical Cassettes have been validated for a maximum load of with the associated instruments:

The worst-case recommended load is 412g.

The device dimensions are listed below for Anthogyr Surgical Cassettes:

- INMODOPS3, INMODOPS3V, INMODOPS3L, INMODOPS3LV, INMODOPP3, INMODOPP3V: 130x155x47 mm

- INMODIGM, INMODIGMV: 76x155x47 mm

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

Technological Characteristics

The subject devices and predicate devices K160730 and K203618 share the following characteristics:

- Identical indications for use
- Identical Product code
- Identical Design

- Identical Material
- Identical Materials compatible with sterilization method
- Identical Perforated
- Identical Reusable
- Identical Sterilization Method
- Identical Cycles
- Identical Parameters
- Identical Sterile Barrier
- Identical Biocompability
- Equivalent vent to volume

The difference between the primary predicate device with the Anthogyr Surgical Cassettes subject devices are in the Table 1:

	Number of brackets in the cassette
Primary Predicate Device: (K160730)	33
Subject devices: INMODOPS3L/ INMODOPS3LV	37
Subject devices: INMODOPS3/ INMODOPS3V	37
Subject devices: INMODOPP3/ INMODOPP3V	21
Subject devices: INMODIGM/ INMODIGMV	12

Table 1 – Difference between the primary predicate device with the Anthogyr Surgical Cassettes subject devices

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

K230680 – Traditional 510(k)

Anthogyr Surgical Cassettes

510(k) Summary

FEATURE	SUBJECT DEVICE K230680 Anthogyr Surgical Cassettes	PRIMARY PREDICATE DEVICE K160730 Instrument Kits	REFERENCE DEVICE K203618 Neodent EasyGuide Kit Cases	Equivalence discussion
Indications for Use	The Anthogyr Surgical 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 is: INMODOPS3, INMODOPS3L, INMODOPP3, INMODIGM, INMODOPS3V, INMODOPS3LV, INMODOPP3V, INMODIGMV: Pre-vacuum steam: 132 °C (270º F) during 4 minutes with 20 minutes drying time The Anthogyr Surgical Cassettes have been validated for a maximum load of with the associated instruments: The worst-case recommended load is 412g. The device dimensions are listed below for Anthogyr Surgical Cassettes: - INMODOPS3, INMODOPS3V, INMODOPS3L, INMODOPS3LV, INMODOPP3, INMODOPP3V: 130x155x47 mm - INMODIGM, INMODIGMV: 76x155x47 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.	I**ndications for Use for GM EasyGuide Surgical Kit Case Narrow/Regular Diam Implants:** Neodent Instrument Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kits are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kits require the use of FDA-cleared wrap to maintain the sterility of the enclosed devices. The Kits are to be enclosed in a sterilization wrap that is FDA-cleared for the indicated cycles, and moist heat (steam) sterilized using one of the following cycles: Fractionated vacuum (pre-vacuum) – Exposure at 132 °C for 4 minutes, 20-minute dry time. Gravity displacement – Exposure at 132 °C for 15 minutes, 20-minute dry time. Neodent Instrument Kits are intended for sterilization of non-porous loads. The combined weight of the GM EasyGuide Surgical Kit Case Narrow/Regular Diam Implants and the associated instruments is 310,18 g. The weight of the empty Kit Case is 263,63 g. Neodent GM EasyGuide Kit Cases should not be stacked during sterilization **Indications for Use for GM EasyGuide Surgical Kit Case Regular/Large Diam Implants:** Neodent Instrument Kits are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kits are intended to allow	**Identical** The subject devices have the same indications for use as the primary predicate. More detail regarding the indication like weight and sterilization condition were added.

FEATURE	SUBJECT DEVICE K230680 Anthogyr Surgical Cassettes	PRIMARY PREDICATE DEVICE K160730 Instrument Kits	REFERENCE DEVICE K203618 Neodent EasyGuide Kit Cases	Equivalence discussion
			sterilization of the enclosed medical devices. Neodent Instrument Kits require the use of FDA-cleared wrap to maintain the sterility of the enclosed devices. The Kits are to be enclosed in a sterilization wrap that is FDA-cleared for the indicated cycles, and moist heat (steam) sterilized using one of the following cycles: Fractionated vacuum (pre-vacuum) – Exposure at 132 °C for 4 minutes, 20-minute dry time. Gravity displacement – Exposure at 132 °C for 15 minutes, 45-minute dry time. Neodent Instrument Kits are intended for sterilization of non-porous loads. The combined weight of the GM EasyGuide Surgical Kit Case Regular/Large Diam Implants and the associated instruments is 346,45 g. The weight of the empty Kit Case is 264,12g. Neodent EasyGuide Kit Cases should not be stacked during sterilization.	
Product code	KCT	KCT	KCT	**Identical** The subject devices have the same product code as the primary predicate and reference devices.
Design	Plastic tray with locking lid and silicone containments brackets	Plastic tray with locking lid and silicone containments brackets	Rigid base and removable inner tray with a lid. Retention grommets.	**Identical** The subject devices have the same design as the primary predicate.
Dimensions	INMODOPS3, INMODOPS3V, INMODOPS3L, INMODOPS3LV, INMODOPP3, INMODOPP3V: 130x155x47 mm INMODIGM, INMODIGMV: 76x155x47 mm	130x155x47 mm 76x155x47 mm	195x90x 64 mm	**Identical** The subject devices have the same dimensions as the primary predicate.

K230680 – Traditional 510(k)

Anthogyr Surgical Cassettes

510(k) Summary

FEATURE	SUBJECT DEVICE K230680 Anthogyr Surgical Cassettes	PRIMARY PREDICATE DEVICE K160730 Instrument Kits	REFERENCE DEVICE K203618 Neodent EasyGuide Kit Cases	Equivalence discussion
Materials	Polyphenylsulfone (Radel R-5000) Polyphenylsulfone (Radel R-5100) Medical grade silicone Stainless steel	Polyphenylsulfone (Radel R-5000) Polyphenylsulfone (Radel R-5100) Medical grade silicone Stainless steel	Polysulfone polymer Polyphenylsulfone Medical grade silicone	**Identical** The subject devices have the same materials as the primary predicate.
Materials compatible with sterilization Method	Yes	Yes	Yes	**Identical** The subject devices have the same materials compatible with sterilization method as the primary predicate and reference devices.
Perforated	Yes; allows moist heat (steam) penetration to achieve sterilization	Yes; allows moist heat (steam) penetration to achieve sterilization	Yes; allows moist heat (steam) penetration to achieve sterilization	**Identical** The subject devices have the same perforated as the primary predicate.
Reusable	Yes, up to 250x	Yes, up to 250x	Yes, up to 100x	**Identical** The subject devices have the same reusable life as the primary predicate.
Sterilization Method	Moist heat (steam) to a SAL of 10^{-6}	Moist heat (steam) to a SAL of 10^{-6}	Moist heat (steam) to a SAL of 10^{-6}	**Identical** The subject devices have the same sterilization method as the primary predicate and reference devices.
Cycles	Pre-Vacuum Steam Sterilization	Fractionated vacuum (pre-vacuum)	Fractionated vacuum (pre-vacuum)	**Identical** The subject devices have the same cycle as the primary predicate and reference devices.
Parameters	Pre-Vacuum: Sterilization temperature: 132º C (270º F). Sterilization time: 4 minutes. Drying time: 20 minutes.	Pre-Vacuum: Sterilization temperature: 134º C (270º F). Sterilization time: 3 minutes. Drying time: 16 minutes.	Pre-Vacuum Sterilization temperature: 132 °C Sterilization time: 4 minutes. Drying time: 20 minutes.	**Identical** The subject devices have the parameter of sterilization as the reference devices.

FEATURE	SUBJECT DEVICE K230680 Anthogyr Surgical Cassettes	PRIMARY PREDICATE DEVICE K160730 Instrument Kits	REFERENCE DEVICE K203618 Neodent EasyGuide Kit Cases	Equivalence discussion
Sterile Barrier	Sterilization wrap, FDA-cleared for indicated method and cycles	Sterilization wrap, FDA-cleared for indicated method and cycles	Sterilization wrap, FDA-cleared for indicated method and cycles	**Identical** The subject devices have the same sterile barrier as the primary predicate and reference devices.
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.	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 devices have the same biocompatibility as the primary predicate and reference devices.

Table 2 – Technological Characteristics Comparison of subject device versus predicate devices

Non-Clinical Performance data

The performance during multiple reprocessing steps for the Anthogyr Axiom® Surgical 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 Anthogyr Surgical Cassettes.

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.	Passed

Standard or Test Method	Purpose of the Testing	Acceptance Criteria	Results
		All positive controls for SAL testing must show characteristic growth of the indicator organism.	
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 250 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

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, Anthogyr Axiom® Surgery Cassettes, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K160730.