DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 27, 2017

Anthogyr
Therese Candau
Regulatory Affairs Manager
2237 Avenue Andre Lasquin
Sallanches, 74700 FR

Re: K160730
Trade/Device Name: Instrument Kits
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 20, 2017
Received: March 24, 2017

Dear Therese Candau:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160730

Device Name
Instrument kits

Indications for Use *(Describe)*
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 cycle of sterilization is:
Pre-vacuum steam: 134 °C during 3 minutes with 16 minutes drying time

Anthogyr does not make any lumen claims for the instrument kits.
The Axiom range surgery kit represents the worst case validated load due to the number of components (34 instruments).
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.

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

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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."

510(k) SUMMARY K160730

5.1 SUBMITTER'S CONTACT INFORMATION

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Contact person: Thérèse CANDAU (m.candau@anthogyr.com)
Preparation date: 04/12/2017

5.2 DEVICE

Trade name: Instrument kits
Classification name: STERILIZATION CASSETTE
Class II
Product Code: KCT
CFR Section: 21CFR 880.6850
Device panel: GENERAL HOSPITAL

5.3 PREDICATE DEVICE

InterActive Complete Surgical Tray (K142519), manufactured by Implant Direct

5.4 DEVICE DESCRIPTION

Instrument kits are cassettes used to enclose and hold surgical instruments and accessories in an organized manner during the sterilization process and subsequent storage. The cassettes by themselves do not maintain sterility. They are to be used with an FDA cleared steam sterilizable pouch.
The cassette is available in only one size (129x156x47.5 mm) marketed in different variations, including different number of tools.
The tools included in the kits are class I exempt or already have class II pre-market notification clearance.
The cassettes are reusable and made of the same materials as the predicate device (Radel R-5000 and R-5100 for tray and lid and medical grade silicone for circular brackets holding the tools).

5.5 INTENDED USE

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 cycle of sterilization is:
Pre-vacuum steam: 134 °C during 3 minutes with 16 minutes drying time
Anthogyr does not make any lumen claims for the instrument kits.
The Axiom range surgery kit represents the worst case validated load due to the number of components (34 instruments).
The cassettes are not intended to be stacked during sterilization process.

5.6 TECHNOLOGICAL CHARACTERISTICS

	ANTHOGYR (K160730) Surgical kits	**Implant Direct (K142519) InterActive Complete Surgical Tray**	**Comparison**
21CFR	880.6850		Same part section
Indications for use	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 InterActive Complete Surgical Tray is designed to hold various dental surgical drills and tools in order to organize, steam sterilize, and transport the instruments between uses. The tray is to be enclosed in an FDA cleared steam sterilizable wrap and sterilized in an FDA cleared sterilizer.	Same indications for use
Raw material	Radel R5000 Radel R5100 Medical grade silicone Stainless steel	Polymer resin Radel-5000 Biomedical grade silicone	Some materials are common. Radel R5100 meets USP class VI requirements and compatibility testing demonstrated safety and efficacy
Design	Plastic tray with locking lid and silicone containments brackets		Same design
Sterilization method	Pre-vacuum steam		Same sterilization method
Reusable	Yes		Both are reusable devices

Material compatibility with sterilization process	Yes		Both devices demonstrate material compatibility with sterilization process
Microbial barrier properties	To be used in conjunction with an approved sterilization pouch		Both are used with an approved sterilization pouch to maintain sterility
Vent/volume ratio	0.049 in^2/in^3	0.184 in^2/in^3	The vent to volume ratio is lower for the candidate device, but sterilant penetration testing demonstrates safety and efficacy

5.7 PERFORMANCE TESTING

Performance characteristics of the device are supported by cleaning validation, sterilization validation and cytotoxicity tests.
No clinical tests were conducted.

Cleaning instructions for reusable devices

Cleaning validations were conducted as per AAMI TIR 30, AAMI TIR 12, ISO 17665 for both manual and automatic cleaning.

Sterilization validation

Sterilization validation was performed with a legally marketed pouch on the most complete instrument kit, taking into account worst case scenarios.
Steam sterilization validations were conducted as per ISO 17665

Drying time

Validated in steam sterilization report according to ISO 17665

Toxicological properties

Cytotoxicity tests were conducted as per ISO 10993-5

Material compatibility

Radel technical data sheet

5.8 CONCLUSION

ANTHOGYR INSTRUMENT KITS are substantially equivalent to their predicate devices in terms of intended use, material, design, mechanical properties and function.

All the kits have the same vent to volume ratio, so the most challenging container to achieve sterilization is the most loaded one.
Non clinical performance testing (sterilization and cleaning validation, cytotoxicity test) according to special control demonstrate that ANTHOGYR INSTRUMENT KITS are as safe, as effective, and perform as safely and effectively as their predicate device.