April 5, 2018

JJGC Industria e Comercio de Materiais Dentarios S.A.
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K171713
Trade/Device Name: Neodent Instrument Kits
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 15, 2018
Received: March 16, 2018

Dear Kevin Thomas:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K. Pamidimukkala -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)*

K171713

Device Name

Neodent Instrument Kits

Indications for Use *(Describe)*

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 GM/WS Surgical Kit Case maximum load weight is 125 grams.

The GM Surgical Kit Case maximum load weight is 113 grams.

Neodent Instrument Kits are recommended not to be stacked during sterilization.

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
K171713
Neodent Instrument Kits
JJGC Indústria e Comércio de Materiais Dentários S.A.

March 23, 2018

ADMINISTRATIVE INFORMATION

Manufacturer Name	JJGC Indústria e Comércio de Materiais Dentários S.A. Av. Juscelino Kubitschek de Oliveira, 3291 – CIC Curitiba, Paraná, 81270-200, Brazil Telephone: +55 41 2169 4058 Fax: +55 41 2169 4061
Official Contact	Julianne de Oliveira Capucho Lechechem Regulatory Affairs Manager
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Neodent Instrument Kits
Common Name	Instrument sterilization trays
Classification Name	Sterilization wrap containers, trays, cassettes, and other accessories
Classification Regulations	21 CFR 880.6850, Class II
Product Code	KCT
Classification Panel	General Hospital
Reviewing Branch	General Hospital

PREDICATE DEVICE INFORMATION

The primary predicate device is K160730, Instrument Kits, Anthogyr.

INDICATIONS FOR USE

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 GM/WS Surgical Kit Case maximum load weight is 125 grams.
The GM Surgical Kit Case maximum load weight is 113 grams.
Neodent Instrument Kits are recommended not to be stacked during sterilization.

SUBJECT DEVICE DESCRIPTION

The subject device kits are reusable rigid containers, comprising a case bottom (or base), a removable inner tray base (tray), and tray lid (lid). The subject device kits are to be used to organize and protect instruments and accessories that are to be sterilized by the healthcare provider. The subject device includes two (2) kits in one size and two (2) inner tray configurations. The lids are manufactured from injection molded polyphenylsulfone, the tray base and case bottoms are manufactured from injection molded polysulfone, and holders of various geometries to position items in the trays are manufactured from molded silicone. The subject device kits are provided nonsterile to the end-user.

Technological Characteristic Comparison Table

	Subject Device	**Primary Predicate Device**	**Comparison**
	K171713 Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	K160730 Instrument Kits Anthogyr	
Indications for Use Statement	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 GM/WS Surgical Kit Case maximum load weight is 125 grams. The GM Surgical Kit Case maximum load weight is 113 grams. Neodent Instrument Kits are recommended not to be stacked during sterilization.	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.	Similar
Product Code	KCT	KCT	Same
Design	Rigid polymer bottom, lid, and removable inner tray	Plastic tray and lid	Similar
Materials	Polysulfone Polyphenylsulfone (Radel R5000) Medical grade silicone	Polyphenylsulfone (Radel R5000, Radel R5100) Medical grade silicone Stainless steel	Similar
Materials compatible with Sterilization Method	Yes	Yes	Same
Perforated	Yes; allows moist heat (steam) penetration to achieve sterilization	Yes; allows moist heat (steam) penetration to achieve sterilization	Same
Reusable	Yes	Yes	Same
Overall dimensions	264 mm L x 163 mm W x 54 mm H	156 mm L x 129 mm W x 47.5 mm H	Similar
Volume to vent ratio	98.04 cm^3 / cm^2 = 38.6 in^3 / in^2	20.41 in^3 / in^2 (Reported as vent to volume ratio = 0.049 in^2 / in^3)	Similar
Vent to volume ratio	0.0102 cm^2 / cm^3 (0.0259 in^2 / in^3)	0.049 in^2 / in^3	Similar
Sterilization Method	Moist heat (steam)	Moist heat (steam)	Same
Cycles	Gravity displacement Fractionated vacuum (pre-vacuum)	Pre-vacuum	Same
Sterile Barrier	Sterilization wrap, FDA-cleared for indicated method and cycles	Sterilization pouch, FDA-cleared for indicated method and cycles	Same

The subject device and the primary predicate device K160730 have the same intended use, the same product classification and product code (KCT), and have similar Indications for Use statements. The subject device and the primary predicate device K160730 are reusable rigid containers used to organize and protect the instruments that are sterilized by the healthcare provider. The subject device and the

predicate K160730 components are perforated to allow for penetration of the sterilant, and are to be used with moist heat (steam) sterilization, and require the use of a FDA-cleared wrap or pouch to maintain sterility. Although the subject device and the primary predicate device K160730 have slightly different Indications for Use language, this difference in language does not change the intended use.

The subject device and the primary predicate K160730 include components manufactured from polyphenylsulfone and silicone.; The subject device and primary predicate device K160730 are provided in one (1) size and two (2) configurations. The subject device and the predicate devices are manufactured from materials with a history biocompatibility and clinical use for the cleared indications. The subject device and the predicate devices are to be used according to the validated labeling (sterilization processes and cycles).

SUMMARY OF NON-CLINCAL PERFORMANCE DATA

Manual cleaning instructions were validated using microbiological, protein, and hemoglobin assays. Sterilization validation, including sterilant penetration and drying time, was performed according to AAMI/ANSI/ISO 17665-1 and ISO TS 17665-2. Life cycle (simulated usage) testing was performed, which included visual inspection, component dimensional fit verification, and functional closure (lid-bottom latch) verification. Biocompatibility testing was performed using methods described in AAMI/ANSI/ISO 10993-5 and ISO 10993-12. No clinical data were included in this submission.

CONCLUSION

The subject device K171713 and the predicate device K160730 have the same intended use, have similar designs and technological characteristics, and are made of similar materials. The data included in this submission demonstrate that the subject device is as safe and as effective as the predicate device.