May 7, 2019

JJGC Industria e Comercio de Materiais Dentarios S.A.
℅ Jennifer Jackson
Director of Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K182865
Trade/Device Name: Neodent Instruments Kits
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: April 8, 2019
Received: April 9, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

For David Krause, PhD
Acting Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182865

Device Name
Neodent Instrument Kits

Indications for Use *(Describe)*

Indications for Use for GM/WS Surgical Kit Case:

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/WS Surgical Kit Case and the associated instruments is 674.5 g. The weight of the empty Kit Case is 507 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.

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

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K182865

Device Name
Neodent Instrument Kits

Indications for Use *(Describe)*

Indications for Use for GM Prosthetic Kit Case:

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 Prosthetic Kit Case and the associated instruments is 250.5 g. The weight of the empty Kit Case is 210 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)

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See PRA Statement below.

510(k) Number *(if known)*

K182865

Device Name
Neodent Instrument Kits

Indications for Use *(Describe)*

Indications for Use for GM Try-In Kit Case:

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 require the use of FDA-cleared wrap to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilizable wrap that is FDA-cleared for the indicated cycles, and moist heat (steam) sterilized using one of the following cycles:
Fractionated vacuum (pre-vaccum) – Exposure at 132 °C for 4 minutes, 20-minute dry time.
Gravity displacement – Exposure at 132 ºC for 15 minutes, 20-minute dry time.
Neodent Instrument Kits are intended for sterilization of non-porous loads.
The combined weight of the GM Try-In Kit Case and the associated instruments is 212.6 g. The weight of the empty Kit Case is 195 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)

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Indications for Use

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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182865

Device Name
Neodent Instrument Kits

Indications for Use *(Describe)*

Indications for Use for GM Guided Surgery Kit Case:

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, 40-minute dry time.
Neodent Instrument Kits are intended for sterilization of non-porous loads.
The combined weight of the GM Guided Surgery Surgical Kit Case and the associated instruments is 728.4 g. The weight of the empty Kit Case is 567 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)

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510(k) Summary
K182865

ADMINISTRATIVE INFORMATION

Sponsor	JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Oliveira, 3291 Curitiba, Parana, Brazil 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person	Jennifer M. Jackson, MS Director of Regulatory Affairs & Quality, Straumann USA E-Mail: jennifer.jackson@straumann.com Telephone (978) 747-2509
Date Prepared	30/Apr/2019
Preparer / Alternate Contact	Mariana Soares Hartmann Regulatory Affairs Analyst E-Mail: mariana.hartmann@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Neodent Instrument Kits
Common Name	Instrument Sterilization Trays
Classification Name	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Classification Regulations	21 CFR 880.6850, Class II
Product Code	KCT
Classification Panel	General Hospital
Reviewing Branch	Infection Control Devices Branch

PREDICATE DEVICE INFORMATION

Predicate Device	K171713 – Neodent Instrument Kits, JJGC Indústria e Comércio de Materiais Dentários AS
Reference Devices	K142529, Genesis™ Reusable Rigid Sterilization Container System, CareFusion 2200 Inc. K180915, Sonicision Reusable Sterilization Tray, Covidien

INDICATIONS FOR USE

Indications for Use for GM/WS Surgical Kit Case:
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/WS Surgical Kit Case and the associated instruments is 674.5 g. The weight of the empty Kit Case is 507 grams.
Neodent Instrument Kits are recommended not to be stacked during sterilization.

Indications for Use for GM Prosthetic Kit Case:
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
The combined weight of the GM Prosthetic Kit Case and the associated instruments is 250.5 g. The weight of the empty Kit Case is 210 grams.
Neodent Instrument Kits are recommended not to be stacked during sterilization.

Indications for Use for GM Try-In Kit Case:
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 require the use of FDA-cleared wrap to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilizable 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 ºC for 15 minutes, 20-minute dry time.
Neodent Instrument Kits are intended for sterilization of non-porous loads.
The combined weight of the GM Try-In Kit Case and the associated instruments is 212.6 g. The weight of the empty Kit Case is 195 grams.
Neodent Instrument Kits are recommended not to be stacked during sterilization.

Indications for Use for GM Guided Surgery Kit Case:
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, 40-minute dry time.
Neodent Instrument Kits are intended for sterilization of non-porous loads.
The combined weight of the GM Guided Surgery Surgical Kit Case and the associated instruments is 728.4 g.
The weight of the empty Kit Case is 567 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 devices include six (6) such kits. The lids are manufactured from injection molded polyphenylsulfone resin, the tray base and case bottoms are manufactured from injection molded polysulfone resin. The designs include grommets of various geometries manufactured from molded silicone that retain the instruments within the tray. Certain designs also incorporate a holder of a single geometry made of Ti-6Al-4V-ELI to position items in the trays. The subject device kits are provided nonsterile to the end- user. The dimensions for each model are presented in the table below:

Assembled set	Assembled Set Dimension (L x W x H)	Component Number	Component Dimension (L x W x H)
110.287	264 x 163 x 54 mm	212.294 (Lid)	264 x 163 x 43 mm
		212.310 (Tray)	248 x 149 x 16 mm
		212.318 (Bottom)	256 x 155 x 22 mm
110.294	195 x 90 x 54 mm	212.293 (Lid)	195 x 90 x 36 mm
		212.321 (Tray)	180 x 76 x 17 mm
		212.197 (Bottom)	188 x 84 x 32 mm
110.295	195 x 90 x 44 mm	212.293 (Lid)	195 x 90 x 36 mm
		212.323 (Tray)	180 x 76 x 17 mm
		212.092 (Bottom)	188 x 84 x 22 mm
110.296	264 x 163 x 58 mm	212.327 (Lid)	264 x 163 x 49 mm
		212.320 (Tray)	248 x 148,5 x 16 mm
		212.328 (Bottom)	256 x 155 x 20,5 mm

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	
	K182865 Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	**K171713** Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	**Comparison**
Indications for Use	**Indications for Use for GM/WS Surgical Kit Case:** 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/WS Surgical Kit Case and the associated instruments is 674.5 g. The weight of the empty Kit Case is 507 grams. Neodent Instrument Kits are recommended not to be stacked during sterilization.	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.	**Similar**

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	Comparison
	K182865 Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	**K171713** Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	
	Indications for Use for GM Prosthetic Kit Case: 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 Prosthetic Kit Case and the associated instruments is 250.5 g. The weight of the empty Kit Case is 210 grams. Neodent Instrument Kits are recommended not to be stacked during sterilization.		

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	
	K182865 Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	**K171713** Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	**Comparison**
	Indications for Use for GM Try-In Kit Case: 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 require the use of FDA-cleared wrap to maintain the sterility of the enclosed devices. The kits are to be enclosed in a sterilizable 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 ºC for 15 minutes, 20-minute dry time. Neodent Instrument Kits are intended for sterilization of non-porous loads. The combined weight of the GM Try-In Kit Case and the associated instruments is 212.6 g. The weight of the empty Kit Case is 195 grams. Neodent Instrument Kits are recommended not to be stacked during sterilization.		

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	
	K182865 Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	**K171713** Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	**Comparison**
	Indications for Use for GM Guided Surgery Kit Case: 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, 40-minute dry time. Neodent Instrument Kits are intended for sterilization of non-porous loads. The combined weight of the GM Guided Surgery Surgical Kit Case and the associated instruments is 728.4 g. The weight of the empty Kit Case is 567 grams. Neodent Instrument Kits are recommended not to be stacked during sterilization.		

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	Comparison
	K182865 Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	**K171713** Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	
Intended 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.	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.	**Same**
Product Code	KCT	KCT	**Same**
Design	Rigid polysulfone polymer base and removable inner tray with a polyphenylsulfone lid. Retention grommets of medical grade silicone. Retention fixtures of titanium alloy.	Rigid polysulfone polymer base and removable inner tray with a polyphenylsulfone lid. Retention grommets of medical grade silicone. Retention fixtures of titanium alloy.	**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	For 110.295: 195 L x 90 W x 44 H, mm For 110.294: 195L x 90 W x 54 H, mm For 110.287: 264L x 163 W x 54 H, mm For 110.296: 264 L x 163 W x 58 H, mm	264 L x 163 W x 54 H, mm	**Similar**
Vent to Volume Ratio	110.296: 0.0093 cm2 / cm3 (0.0236 in2 / in3) 110.287: 0.0102 cm2 / cm3 (0.0259 in2 / in3) 110.294: 0.0191 cm2 / cm3 (0.0485 in2 / in3) 110.295: 0.0247 cm2 / cm3 (0.0627 in2 / in3)	0.0102 cm2 / cm3 (0.0259 in2 / in3)	**Similar**
Useful Life	Yes, reusable up to 100 cycles Assembled/disassembled, cleaned, sterilized Visual inspection Component dimensional fit verification Functional closure (lid-base latch) verification	Yes, reusable up to 100 cycles Assembled/disassembled, cleaned, sterilized Visual inspection Component dimensional fit verification Functional closure (lid-base latch)	**Same**
Biocompatibility	The assessment to Biocompatibility was performed per ISO 10993-1 and testing was performed using methods described in AAMI/ANSI/ISO 10993-5. The results indicate that the subject devices are biocompatible.	The assessment to Biocompatibility was performed per ISO 10993-1 and testing was performed using methods described in AAMI/ANSI/ISO 10993-5. The results indicate that the subject devices are biocompatible.	**Same**
Sterilization Method	Moist heat (steam)	Moist heat (steam)	**Same**

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	
	Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	**K171713** Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	**Comparison**
Cycles	Gravity displacement Fractionated vacuum (pre-vacuum)	Gravity displacement Fractionated vacuum (pre-vacuum)	**Same**
Parameters	Gravity Sterilization temperature: 132 °C Sterilization time: 15 minutes; Drying time: 20 minutes or 40 minutes (model number 110.296) Pre-Vacuum Sterilization temperature: 132 °C Sterilization time: 4 minutes; Drying time: 20 minutes.	Gravity Sterilization temperature: 132 °C Sterilization time: 15 minutes; Drying time: 20 minutes Pre-Vacuum Sterilization temperature: 132 °C Sterilization time: 4 minutes; Drying time: 20 minutes.	**Similar**

The subject devices and the primary predicate device K171713 have the same intended use, the same product classification and product code (KCT) and have same Indications for Use statements. The subject devices (and the primary predicate device per K171713) are reusable rigid containers used to organize and protect the dental surgical instruments that are sterilized by the healthcare provider. The subject device and the primary predicate device K171713 components are perforated to allow for penetration of the moist heat (steam) sterilant and require the use of an FDA-cleared wrap or pouch to maintain sterility.

The subject device and the primary predicate device K171713 include components manufactured from polyphenylsulfone, polysulfone and silicone. The subject device also contains a holder fabricated from titanium alloy; while this differs from the predicate it is noted that certain instruments to be contained within the predicate cleared in K171713 are made of the same alloy. The subject device is provided in multiple sizes and configurations, whereas the primary predicate device K171713 is provided in a single size and two configurations.

The reference device cleared in K14259 was used to support the device dimensions and vent to volume ratio. The reference device cleared inK180915 was used to support the sterilization drying time of 40 minutes.

NON-CLINICAL PERFORMANCE DATA

Standard or Test Method	Purpose of the Testing	Results
Custom	Manual cleaning validation	Passed
ANSI/AAMI/ISO 17665-1 ANSI/AAMI/ISO 17665-2	Sterilization validation, including sterilant penetration and drying time	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	Passed
ANSI/AAMI/ISO 10993-5 (Cytotoxicity)	Cytotoxicity testing	Passed

CONCLUSION

The conclusions drawn from the nonclinical data demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device K171713.