December 23, 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: K190665
Trade/Device Name: Neodent Instrument Kit Cases
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: KCT
Dated: October 11, 2019
Received: October 15, 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/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,

Sreekanth Gutala, Ph.D.
Acting Assistant Director for the Sterility Devices Team
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)*

K190665

Device Name
Neodent Instrument Kit Cases

Indications for Use *(Describe)*

Indications for Use for GM Zygomatic Surgical Kit Case:

Neodent Instrument Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kit Cases are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kit Cases 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
Neodent Instrument Kit Cases are intended for sterilization of non-porous loads.
The GM Zygomatic Surgical Kit Case maximum load weight is 220 grams.
Neodent Instrument Kit Cases should 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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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)*

K190665

Device Name
Neodent Instrument Kit Cases

Indications for Use *(Describe)*

Indications for Use for GM Helix LG Compact Surgical Kit Case:

Neodent Instrument Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kit Cases are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kit Cases 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 Kit Cases are intended for sterilization of non-porous loads.
The combined weight of the GM Helix LG Compact Kit Case and the instruments is 297.3 g. The weight of the empty kit case is 236 g.
Neodent Instrument Kit Cases should 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.

510(k) Summary

K190665

ADMINISTRATIVE INFORMATION

Sponsor	JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Olivera, 3291 Curitiba, Parana, Brazil 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person	Jennifer M. Jackson, MS Director of Regulatory Affairs Straumann USA jennifer.jackson@straumann.com Telephone (978) 747-2509
Date Prepared	17/Dec/2019
Preparer / Alternate Contact	Luiza Vaccari Toppel Regulatory Affairs Coordinator luiza.toppel@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

Primary 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 Zygomatic Surgical Kit Case:

Neodent Instrument Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kit Cases are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kit Cases 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, 30-minute dry time
Neodent Instrument Kit Cases are intended for sterilization of non-porous loads.
The combined weight of the GM Zygomatic Surgical Kit Case and the instruments is 738.1 g. The weight of the empty kit case is 515 g.
Neodent Instrument Kit Cases should not to be stacked during sterilization.

Indications for Use for GM Helix LG Compact Surgical Kit Case:

Neodent Instrument Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kit Cases are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kit Cases 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 Kit Cases are intended for sterilization of non-porous loads.
The combined weight of the GM Helix LG Compact Kit Case and the instruments is 297.3 g. The weight of the empty kit case is 236 g.
Neodent Instrument Kits should not to be stacked during sterilization.

SUBJECT DEVICE DESCRIPTION

The subject device kit cases are reusable rigid containers, comprising a case bottom (or base), a removable inner 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 two (2) such kit cases. The lids are manufactured from injection molded polyphenylsulfone resin, the tray and base are manufactured from injection molded polysulfone resin. The designs include grommets and inserts of various geometries manufactured from molded silicone that retain the instruments within the tray and base. The subject device kit cases are provided nonsterile to the end-user. The dimensions for each part of the model and the overall dimensions are presented in the table below:

Assembled Kit Case	Description	Assembled Kit Case Dimension (L x W x H)	Component Number	Component Dimension (L x W x H)
110.299	GM Zygomatic Surgical Kit Case	264 x 163 x 58 mm	212.327 (Lid)	264 x 163 x 49, mm
			212.345 (Tray)	248 x 149 x 16, mm
			212.347 (Base)	256 x 155 x 20.5, mm
110.300	GM Helix LG Compact Surgical Kit Case	195 x 90 x 64 mm	212.293 (Lid)	195 x 90 x 36, mm
			212.346 (Tray)	180 x 76 x 26.5, mm
			212.348 (Base)	188 x 84 x 42, mm

Note: The instrument and accessory devices that are sterilized and stored within the subject Kit Cases are not the subject devices of this submission.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	COMPARISON
	K190665 Neodent Instrument Kit Cases 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 Statement	**Indications for Use for GM Zygomatic Surgical Kit Case:** Neodent Instrument Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kit Cases are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kit Cases 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, 30-minute dry time Neodent Instrument Kit Cases are intended for sterilization of non-porous loads. The combined weight of the GM Zygomatic Surgical Kit Case and the instruments is 738.1 g. The weight of the empty kit case is 515 g. Neodent Instrument Kit Cases are recommended not to be stacked during sterilization. **Indications for Use for GM Helix LG Compact Surgical Kit Case:** Neodent Instrument Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kit Cases are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kit Cases 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 Kit Cases are intended for sterilization of non-porous loads. The combined weight of the GM Helix LG Compact Kit Case and the instruments is 297.3 g. The weight of the empty kit case is 236 g. Neodent Instrument Kit Cases 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
	K190665 Neodent Instrument Kit Cases 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 Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Neodent Instrument Kit Cases are intended to allow sterilization of the enclosed medical devices. Neodent Instrument Kit Cases 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**
Design	Rigid polysulfone polymer base and removable inner tray with a polyphenylsulfone lid. Retention grommets of medical grade silicone.	Rigid polysulfone polymer base and removable inner tray with a polyphenylsulfone lid. Retention grommets of medical grade silicone.	**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	GM Zygomatic Surgical Kit Case: 264 L x 163 W x 56 H, mm GM Helix LG Compact Surgical Kit Case: 195 L x 90 W x 64 H, mm	264 L x 163 W x 54 H, mm	**Similar**
Vent to Volume Ratio	GM Zygomatic Surgical Kit Case: 0.0093 cm^2 / cm^3 (0.0236 in^2 / in^3) GM Helix LG Compact Surgical Kit Case: 0.0157 cm^2 / cm^3 (0.0400 in^2 / in^3)	0.0102 cm^2 / cm^3 (0.0259 in^2 / in^3)	**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) verification	**Same**
Biocompatibility	The kit cases are not intended to be in contact with the patient.	The kit cases are not intended to be in contact with the patient.	**Same**
Sterilization Method	Moist heat (steam)	Moist heat (steam)	**Same**
Cycles	Gravity displacement (only for GM Helix LG Compact Surgical Kit Case) Fractionated vacuum (pre-vacuum)	Gravity displacement Fractionated vacuum (pre-vacuum)	**Same**
Parameters	<u>Gravity (only for model number 110.300)</u> Sterilization temperature: 132 °C Sterilization time: 15 minutes Drying time: 20 minutes <u>Pre-Vacuum</u> Sterilization temperature: 132 °C Sterilization time: 4 minutes; Drying time: 30 minutes (model number 110.299) or 20 minutes (model number 110.300)	<u>Gravity</u> Sterilization temperature: 132 °C Sterilization time: 15 minutes; Drying time: 20 minutes <u>Pre-Vacuum</u> Sterilization temperature: 132 °C Sterilization time: 4 minutes; Drying time: 20 minutes.	**Similar** All validated cycles provide similar sterilization efficacy. (minimum SAL of 10^{-6})

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	COMPARISON
	K190665 Neodent Instrument Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	**K171713** Neodent Instrument Kits JJGC Indústria e Comércio de Materiais Dentários S.A.	
Sterile Barrier	Sterilization wrap, FDA-cleared for indicated method and cycles	Sterilization pouch, FDA-cleared for indicated method and cycles	**Same**

The subject devices and the primary predicate device per K171713 have the same intended use and have equivalent Indications for Use Statements. The subject devices (and the primary predicate device per K171713) are reusable rigid containers used to organize and protect 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.

NON-CLINICAL 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 ANSI/AAMI/ISO 17665-1 and 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 ANSI/AAMI/ISO 10993-5 (cytotoxicity). No clinical data were included in this submission.

Standard or Test Method	Purpose of the Testing	Acceptance Criteria	Results
Custom	Manual cleaning validation	Hemoglobin Test: • <0.50 µg/mL • <55 µg/article • <0.0078 µg/cm^2 Micro BCA Protein Test: • <1.1 µg/mL • <220 µg/article • <0.018 µg/cm^2	Passed
ANSI/AAMI/ISO 17665-1 ANSI/AAMI/ISO 17665-2	Sterilization validation, including sterilant penetration and drying time	SAL of 10^{-6}	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	Visual and functional inspection following 100 cycles	Passed
ANSI/AAMI/ISO 10993-5 (Cytotoxicity)	Cytotoxicity testing	<30% inhibition of proliferation of protein content	Passed

CONCLUSION

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