April 13, 2022

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

Re: K214051
Trade/Device Name: Neodent Implant System-Helix NGM Compact Surgical Kit Cases
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 18, 2022
Received: March 23, 2022

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,

Clarence W. Murray, III, PhD
Assistant 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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K214051

Device Name
Neodent Implant System - Helix NGM Compact Surgical Kit Cases

Indications for Use *(Describe)*

Helix NGM Compact Surgical Kit Cases are indicated for organization of surgical and/or prosthetic instruments during sterilization, storage and transport. The use of this product facilitates storage and organization of instruments during and after surgical procedures.
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 Surgical Kit Case and the associated instruments is 268.0 g. The weight of the empty Kit Case is 208.15 grams. Neodent Instrument Kit Cases should not 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

ADMINISTRATIVE INFORMATION

Sponsor	JJGC Indústria e Comércio de Materiais Dentários SA (dba Neodent) 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, Straumann USA E-mail: jennifer.jackson@straumann.com Telephone (978) 747-2509
Date Prepared	5/Apr/2022
Preparer / Alternate Contact	Mariana Hartmann Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA E-mail: mariana.hartmann@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Neodent Implant System – Helix NGM Compact Surgical Kit Cases
Common Name	Instrument Sterilization Trays
Classification Name	Sterilization Wrap Containers, Trays, Cassettes & Other
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	K192670 – Neodent Instrument Kit Cases, JJGC Indústria e Comércio de Materiais Dentários S.A

INDICATIONS FOR USE

Indications for Use for Helix NGM Compact Surgical Kit Case and Pre-Mounted Helix NGM Compact Surgical Kit Case:

Helix NGM Compact Surgical Kit Cases are indicated for organization of surgical and/or prosthetic instruments during sterilization, storage and transport. The use of this product facilitates storage and organization of instruments during and after surgical procedures.
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 Surgical Kit Case and the associated instruments is 268.0 g. The weight of the empty Kit Case is 208.15 grams. Neodent Instrument Kit Cases should not 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 kit cases are manufactured in autoclavable polymer. The design of the subject devices include grommets manufactured from medical grade silicone that retain the instruments within the tray. They also presents markings that guide instrument use during procedures. 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)
110.315	Helix NGM Compact Surgical Kit Case	195 x 90 x 54 mm	212.293 (Lid)	195 x 90 x 36 mm
			704346 (Tray)	180 x 76 x 16.5 mm
			704345 (Base)	188 x 84 x 32 mm
110.316	Pre-Mounted Helix NGM Compact Surgical Kit Case	195 x 90 x 54 mm	212.293 (Lid)	195 x 90 x 36 mm
			704346 (Tray)	180 x 76 x 16.5 mm
			704345 (Base)	188 x 84 x 32 mm

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

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	COMPARISON
	Helix NGM Compact Surgical Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	**K192670** Neodent Instrument Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	
Indications for Use Statement	**Indications for Use for Helix NGM Compact Surgical Kit Case** Helix NGM Compact Surgical Kit Cases are indicated for organization of surgical and/or prosthetic instruments during sterilization, storage and transport. The use of this product facilitates storage and organization of instruments during and after surgical procedures. 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 Surgical Kit Case and the associated instruments is 268.0 g. The weight of the empty Kit Case is 208.15 grams. Neodent Instrument Kit Cases should not be stacked during sterilization. **Indications for Use for Pre-Mounted Helix NGM Compact Surgical Kit Case** Product indicated for conditioning and safe fastening surgical and/or prosthetic instruments during their use and sterilization. The use of this product facilitates storage and organization of instruments during and after surgical procedures. 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 Surgical Kit Case and the associated instruments is 268.0 g. The weight of the empty Kit Case is 208.15 grams. Neodent Instrument Kit Cases should not be stacked during sterilization.	**Indications for Use for GM 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, 40-minute dry time. Neodent Instrument Kit Cases are intended for sterilization of non-porous loads. The combined weight of the GM Surgical Kit Case and the associated instruments is 613.1 g. The weight of the empty Kit Case is 510 grams. Neodent Instrument Kit Cases should not to be stacked during sterilization. **Indications for Use for GM Helix 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 Compact Surgical Kit Case and the associated instruments is 308.2 g. The weight of the empty Kit Case is 231 grams. Neodent Instrument Kit Cases should not to be stacked during sterilization.	**Similar**

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	COMPARISON
	Helix NGM Compact Surgical Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	**K192670** Neodent Instrument Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	
Intended Use	The Helix Narrow GM Compact Surgical Kit Cases is suitable for safe storage of surgical and prosthetic instruments, organizing the instruments in the sequence in which they will be used, as well as for sterilization of such instruments.	The GM Helix Compact Surgical Kit Case is suitable for safe storage of surgical and prosthetic instruments, organizing the instruments in the sequence in which they will be used, as well as for sterilization of such instruments.	**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.	**Identical**
Perforated	Yes; allows moist heat (steam) penetration to achieve sterilization	Yes; allows moist heat (steam) penetration to achieve sterilization	**Identical**
Reusable	Yes	Yes	**Identical**
Overall dimensions	110.315: 195 L x 90 W x 54 H, mm 110.316: 195 L x 90 W x 54 H, mm	110.288: 264 L x 163 W x 54 H, mm 110.297: 195 L x 90 W x 64 H, mm	**Similar**
Volume to Vent Ratio	110.315: 52.3 cm^3/ cm^2 (20.59 in^3/ in^2) 110.316: 52.3 cm^3/ cm^2 (20.59 in^3/ in^2)	110.288: 98.04 cm^3/ cm^2 (38.6 in^3/ in^2) 110.297: 63.5 cm^3/ cm^2 (25.0 in^3/ in^2)	**Similar**
Useful Life	Yes, reusable up to 100 cycles	Yes, reusable up to 100 cycles	**Identical**
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) to a SAL of 10^{-6}	Moist heat (steam) to a SAL of 10^{-6}	**Identical**
Cycles	Gravity displacement Fractionated vacuum (pre-vacuum)	Gravity displacement Fractionated vacuum (pre-vacuum)	**Same**
Parameters	<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.	<u>Gravity</u> Sterilization temperature: 132 °C Sterilization time: 15 minutes; Drying time: 40 minutes (model number 110.288) or 20 minutes (model number 110.297) <u>Pre-Vacuum</u> Sterilization temperature: 132 °C Sterilization time: 4 minutes; Drying time: 20 minutes.	**Similar**
Sterile Barrier	Sterilization wrap, FDA-cleared for indicated method and cycles	Sterilization pouch, FDA-cleared for indicated method and cycles	**Identical**

The subject devices and the primary predicate device per K192670 have same intended use and similar Indications for Use Statements. The subject devices and the primary predicate devices 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 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 devices and the primary predicate devices include components manufactured from polyphenylsulfone and polysulfone. The subject devices have the same size, whereas the primary predicate device is provided in two different size and configurations. The overall dimensions of the subject device are similar to the range of overall dimensions cleared for the predicate devices.

NON-CLINICAL PERFORMANCE DATA

Standard or Test Method	Purpose of the Testing	Acceptance Criteria	Results
Custom	Manual cleaning validation • 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
ANSI/AAMI/ISO 17665-1 ANSI/AAMI/ISO 17665-2	Sterilization validation, including sterilant penetration and drying time	All Biological Indicators must be incubated for at least 7 days at 55-60°C. All positive controls for SAL testing must show characteristic growth of the indicator organism.	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	The tested samples must withstand 100 cycles of use (cleaning, sterilization, and functional tests) without compromising their functionalities	Passed
ANSI/AAMI/ISO 10993-5 (Cytotoxicity)	Cytotoxicity testing	Less than 30% cell proliferation inhibition	Passed

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the device in K214051, is as safe, as effective, and performs as well as or better than the legally marketed device (K192670).