August 23, 2024

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

Re: K241492
Trade/Device Name: Zirconia and Nuvo CF Guided Surgery Kit Cases
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: May 28, 2024
Received: May 28, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.08.23 12:50:29 -04'00'

for: Christopher Dugard
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241492

Device Name
Zirconia and Nuvo CF Guided Surgery Kit Cases

Indications for Use *(Describe)*

Zirconia Guided Surgery Kit Cases:
Zirconia Guided Surgery Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Zirconia Guided Surgery Kit Cases are intended to allow sterilization of the enclosed medical devices. Zirconia Guided Surgery 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: Dynamic Air Removal (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. Zirconia Guided Surgery Kit Cases are intended for sterilization of non-porous loads. The combined weight of the Zirconia Guided Surgery Kit Case and the associated instruments is 342.2 g. The weight of the empty Kit is 236.8 grams. Zirconia Guided Surgery Kit Case are recommended not to be stacked during sterilization.

Nuvo CF Guided Surgery Kit Cases:
Nuvo CF Guided Surgery Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Nuvo CF Guided Surgery Kit Cases are intended to allow sterilization of the enclosed medical devices. Nuvo CF Guided Surgery 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, drying for 20 minutes. Gravity displacement: exposure at 132°C for 15 minutes, drying for 30 minutes. Nuvo CF Guided Surgery Kit Cases are intended for sterilization of non-porous loads. The combined weight of the Nuvo CF Guided Surgery Kit Cases and the associated instruments is approximately 693 g. The weight of the empty case is 487 grams. Nuvo CF Guided Surgery Kit Cases are not recommended 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.

Traditional 510(k) Submission

Zirconia and Nuvo CF Guided Surgery Kit Cases

510(k) Summary - K241492

1 510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810, USA Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: JJGC Indústria e Comércio de Materiais Dentários S.A. (dba Neodent) Av. Juscelino Kubitschek de Oliveira, 3291 - CIC Curitiba, Paraná, Brazil 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person:	Jennifer M. Jackson, MS, RAC Sr. Director, Regulatory Affairs and Quality Email: jennifer.jackson@straumann.com Phone Number: +1 978 747-2509 Fax Number: +1 978 747-0023
Prepared By & Alternate Contact:	Leticia Milani Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA E-mail: leticia.milani@neodent.com Phone Number: +5 541 216-9485
Date Prepared:	August 22, 2024

Name of the Device

Trade Names:	Zirconia and Nuvo CF Guided Surgery Kit Cases
Common Name:	Instrument Sterilization Trays
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other
Regulation Number:	21 CFR 880.6850, Class II, Sterilization wrap
Device Classification:	II
Product Code(s):	KCT
Classification Panel:	General Hospital

Traditional 510(k) Submission

Zirconia and Nuvo CF Guided Surgery Kit Cases

510(k) Summary - K241492

Predicate Device(s)

Primary Predicate:

- *K203618 – Neodent EasyGuide Kit Cases (JJGC Indústria e Comércio de Materiais Dentários S.A)*

Reference Devices:

- *K182865 – Neodent Instrument Kits (JJGC Indústria e Comércio de Materiais Dentários S.A)*
- *K223662 – Neodent Implant System – Helix Short Surgical Kit Cases (JJGC Indústria e Comércio de Materiais Dentários S.A)*

Device Description

The Zirconia and Nuvo CF Guided Surgery Kit Cases subject to this submission are reusable rigid containers, composed by a case bottom, a removable inner tray and a lid, which are made of autoclavable polymer. They are indicated to hold various dental instruments (not subject of this submission) in order to organize, sterilize and protect them. Sterilization via moist heat (steam) is performed by the healthcare provider.

Intended Use

The Zirconia and Nuvo CF Guided Surgery Kit Cases are used to safe storage and securing of instruments during sanitization, sterilization and surgical procedures. The Zirconia Guided Surgery Kit Cases are designed for storing the instruments used to install Bone Level (BL) ceramic implants. The Nuvo CF Guided Surgery Kit Cases are intended for the installation of Nuvo CF implants.

Indications for Use

Zirconia Guided Surgery Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Zirconia Guided Surgery Kit Cases are intended to allow sterilization of the enclosed medical devices. Zirconia Guided Surgery 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: Dynamic Air Removal (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. Zirconia Guided Surgery Kit Cases are intended for sterilization of non-porous loads. The combined weight of the Zirconia Guided Surgery Kit Case and the associated instruments is 342.2

g. The weight of the empty Kit is 236.8 grams. Zirconia Guided Surgery Kit Case are recommended not to be stacked during sterilization.

Nuvo CF Guided Surgery Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Nuvo CF Guided Surgery Kit Cases are intended to allow sterilization of the enclosed medical devices. Nuvo CF Guided Surgery 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, drying for 20 minutes. Gravity displacement: exposure at 132°C for 15 minutes, drying for 30 minutes. Nuvo CF Guided Surgery Kit Cases are intended for sterilization of non-porous loads. The combined weight of the Nuvo CF Guided Surgery Kit Cases and the associated instruments is approximately 693 g. The weight of the empty case is 487 grams. Nuvo CF Guided Surgery Kit Cases are not recommended to be stacked during sterilization.

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in the following tables:

Table 1 – Comparison of subject device (Zirconia Guided Surgery Kit Cases) and predicate device

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number	**K241492** Zirconia Guided Surgery Kit Cases	***K203618*** ***Neodent EasyGuide Kit Cases***	***K223662*** ***Helix Short Surgical Kit Cases***	
Indications for Use Statement	Zirconia Guided Surgery Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Zirconia Guided Surgery Kit Cases are intended to allow sterilization of the enclosed medical devices. Zirconia Guided Surgery 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: Dynamic Air Removal (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. Zirconia Guided Surgery Kit Cases are intended for sterilization of non-porous loads. The combined weight of the Zirconia Guided Surgery Kit Case and the associated instruments is 342.2 g. The weight of the empty Kit is 236.8 grams. Zirconia Guided Surgery Kit Case 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 combined weight of the GM EasyGuide Surgical Kit Case Narrow/Regular and the associated instruments is 310,18 g. The weight of the empty Kit Case is 263,63 g. Neodent GM EasyGuide Kit Cases should not be stacked during sterilization.	HS Surgical Kit Cases are indicated for the organization of surgical and/or prosthetic instruments during sterilization, storage, and transport. Use of this product facilitates the storage and organization of instruments during and after surgical procedures. Neodent instrument kit cases are intended to allow sterilization of the medical devices included. Neodent instrument kit cases must be wrapped in FDA-approved materials to maintain the sterility of the devices included. The kits should be placed in an FDA-approved sterilization wrap for the indicated cycles and sterilized by moist heat (steam) using one of the following cycles: Dynamic Air Removal (pre-vacuum): exposure at 132°C for 4 minutes, drying for 30 minutes. Gravity displacement: exposure at 132°C for 15 minutes, drying for 50 minutes. Neodent instrument kit cases are intended for sterilization of non-porous fillers. The combined weight of the HS Surgical Kit case and associated instruments is 302.88 grams. The weight of the empty case is approximately 214.85 grams. Neodent instrument kit cases should not be stacked during sterilization.	**Similar** The subject and primary predicate devices present the same indications for use, being both intended to allow sterilization of the enclosed medical devices. The reference predicate device has a slightly different language, but the indications for use are similar. All devices are intended to enclose other medical devices that are to be sterilized by a health care provider.

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number	**K241492** Zirconia Guided Surgery Kit Cases	***K203618*** ***Neodent EasyGuide Kit Cases***	***K223662*** ***Helix Short Surgical Kit Cases***	
Material and design	Rigid polyphenylsulfone (PPSU) polymer base and removable inner tray with a polyphenylsulfone (PPSU) lid. Retention grommets of medical grade silicone.	Rigid polysulfone (PSU) polymer base and removable inner tray with a polyphenylsulfone (PPSU) lid. Retention grommets of medical grade silicone.	Rigid polysulfone (PSU) polymer base and removable inner tray with a polyphenylsulfone (PPSU) lid. Retention grommets of medical grade silicone.	**Similar** The subject and predicate devices are made of the same material. Despite the subject devices presenting a difference in base and tray composition, the PPSU material has already been used before in devices cleared by FDA. Furthermore, this material change does not interfere with the biocompatibility and performance of the new products.
Perforated	Yes	Yes	Yes	**Same**
Overall dimensions	195 L x 90 W x 67 H, mm	195 L x 90 W x 64 H, mm	195 L x 90 W x 67 H, mm	**Similar** The subject, primary predicate and reference devices have the same dimensions. The small difference between the height of subject and primary predicate device does not compromise safety and efficacy as is better discussed along this submission.
Reusable	Yes, reusable up to 100 cycles	Yes, reusable up to 100 cycles	Yes, reusable up to 100 cycles	**Same**
Volume to Vento Ratio	64.8 cm^3/ cm^2 (25.5 in^3/ in^2)	63.5 cm^3/ cm^2 (25.0 in^3/ in^2)	64.8 cm^3/ cm^2 (25.5 in^3/ in^2)	**Similar** The subject and primary predicate device have a slight difference in volume to vent rate, which does not compromise safety and efficacy, as is proved by the presented sterilization validation.
Sterilization Method	Moist heat (steam) to a SAL of 10^{-6}	Moist heat (steam) to a SAL of 10^{-6}	Moist heat (steam) to a SAL of 10^{-6}	**Same**
Cycles and parameters	Fractionated vacuum (pre-vacuum): Sterilization temperature: 132 °C; Sterilization time: 4 minutes; Drying time: 20 minutes. Gravity displacement: Sterilization temperature: 132 °C; Sterilization time: 15 minutes; Drying time: 20 minutes.	Fractionated vacuum (pre-vacuum): Sterilization temperature: 132 °C; Sterilization time: 4 minutes; Drying time: 20 minutes. Gravity displacement: Sterilization temperature: 132 °C; Sterilization time: 15 minutes; Drying time: 20 minutes.	Fractionated vacuum (pre-vacuum): Sterilization temperature: 132 °C; Sterilization time: 4 minutes; Drying time: 30 minutes. Gravity displacement: Sterilization temperature: 132 °C; Sterilization time: 15 minutes; Drying time: 50 minutes.	**Similar** The subject devices have the same cycle parameters already cleared for the predicate devices, however the reference predicate device requires a longer drying cycle.

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number	**K241492** Zirconia Guided Surgery Kit Cases	***K203618*** ***Neodent EasyGuide Kit Cases***	***K223662*** ***Helix Short Surgical Kit Cases***	
Sterile Barrier	Sterilization wrap, FDA-cleared for indicated method and cycles	Sterilization wrap, FDA-cleared for indicated method and cycles	Sterilization wrap, FDA-cleared for indicated method and cycles	**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. 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. 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. Results indicate that the subject devices are biocompatible.	**Same**

Table 2 – Comparison of subject device (Nuvo CF Guided Surgery Kit Cases) and predicate device

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number	**K241492** Nuvo CF Guided Surgery Kit Cases	***K203618*** ***Neodent EasyGuide Kit Cases***	***K182865*** ***Neodent Instrument Kits***	
Indications for Use Statement	Nuvo CF Guided Surgery Kit Cases are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. Nuvo CF Guided Surgery Kit Cases are intended to allow sterilization of the enclosed medical devices. Nuvo CF Guided Surgery 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, drying for 20 minutes. Gravity displacement: exposure at 132°C for 15 minutes, drying for 30 minutes. Nuvo CF Guided Surgery Kit Cases are intended for sterilization of non-porous loads. The combined weight of the Nuvo CF Guided Surgery Kit Cases and the associated instruments is approximately 693 g. The weight of the empty case is 487 grams. Nuvo CF Guided Surgery Kit Cases are not recommended 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 combined weight of the GM EasyGuide Surgical Kit Case Narrow/Regular and the associated instruments is 310,18 g. The weight of the empty Kit Case is 263,63 g. Neodent GM EasyGuide Kit Cases should not 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, 40-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.	**Similar** Although the language in the indications for use of the subject and primary predicate devices is slightly different, the indications for use are similar in that they are used to enclose instruments to be sterilized by the health care provider.
Material and design	Rigid polyphenylsulfone (PPSU) polymer base and removable inner tray with a polyphenylsulfone (PPSU) lid. Retention grommets of medical grade silicone.	Rigid polysulfone (PSU) polymer base and removable inner tray with a polyphenylsulfone (PPSU) lid. Retention grommets of medical grade silicone.	Rigid polysulfone (PSU) polymer base and removable inner tray with a polyphenylsulfone (PPSU) lid. Retention grommets of medical grade silicone.	**Similar** The subject, primary predicate and reference devices are made of the same material. Despite the subject devices presenting a difference in base and tray composition, the PPSU material has already been used before in devices cleared by FDA. Furthermore, this material change does not interfere with the biocompatibility and performance of the new products.
Perforated	Yes	Yes	Yes	**Same**

FEATURE	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
K Number	**K241492** Nuvo CF Guided Surgery Kit Cases	***K203618*** ***Neodent EasyGuide Kit Cases***	***K182865*** ***Neodent Instrument Kits***	
Overall dimensions	264 L x 163 W x 58 H, mm		264 L x 163 W x 58 H, mm	**Same**
Reusable	Yes, reusable up to 100 cycles	Yes, reusable up to 100 cycles	Yes, reusable up to 100 cycles	**Same**
Volume to Vento Ratio	107.5 cm^3/ cm^2 (42.32 in^3/ in^2)		107.5 cm^3/ cm^2 (42.32 in^3/ in^2)	**Same**
Sterilization Method	Moist heat (steam) to a SAL of 10^{-6}	Moist heat (steam) to a SAL of 10^{-6}	Moist heat (steam) to a SAL of 10^{-6}	**Same**
Cycles and parameters	Fractionated vacuum (pre-vacuum): Sterilization temperature: 132 °C; Sterilization time: 4 minutes; Drying time: 20 minutes. Gravity displacement: Sterilization temperature: 132 °C; Sterilization time: 15 minutes; Drying time: 30 minutes.	Fractionated vacuum (pre-vacuum): Sterilization temperature: 132 °C; Sterilization time: 4 minutes; Drying time: 20 minutes. Gravity displacement: Sterilization temperature: 132 °C; Sterilization time: 15 minutes; Drying time: 20 minutes.	Fractionated vacuum (pre-vacuum): Sterilization temperature: 132 °C; Sterilization time: 4 minutes; Drying time: 40 minutes. Gravity displacement: Sterilization temperature: 132 °C; Sterilization time: 15 minutes; Drying time: 40 minutes.	**Similar** The subject devices have the same cycle parameters already cleared for the primary predicate and reference device, however the reference predicate device requires a longer drying cycle.
Sterile Barrier	Sterilization wrap, FDA-cleared for indicated method and cycles	Sterilization wrap, FDA-cleared for indicated method and cycles	Sterilization wrap, FDA-cleared for indicated method and cycles	**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. 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. 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. Results indicate that the subject devices are biocompatible.	**Same**

Non-Clinical Performance Data

To evaluate the performance of the subject kit cases, the tests described in the following table were performed.

Standard or Test Method	Purpose of the Testing	Acceptance Criteria	Results
ANSI/AAMI/ISO 17665-1 ANSI/AAMI/ISO 17665-2	Steam 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
AAMI TIR 30:2011	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/cm^2 • Protein Test: <6.4 µg/cm^2	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	Biocompatibility of subject devices via cytotoxicity testing	Less than 30% cell proliferation inhibition	Passed

Manual cleaning and sterilization validation

Manual cleaning of the subject kit cases following the manufacturer's recommended cleaning procedures has been validated according to AAMI TIR30:2011. Six simulated use cycles consisting of contamination, cleaning and sterilization were performed. All test method acceptance criteria were met for visual inspection and residuals levels.

Sterilization of the subject kit cases via steam process in autoclave has been validated according to ISO 17665 – 1 "Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routine of a Sterilization Process for Medical Devices using the "Overkill" method to demonstrate the achievement of a sterility assurance level (SAL) of 10^{-6}". A minimum Sterility Assurance Level (SAL) of 1 x 10^{-6} has been validated.

Life Cycle Testing

Life cycle testing of the subject kit cases was performed to validate the recommendations provided by the manufacturer in the Instructions for Use. The reference method consists of cleaning and sterilization cycles (simulated usage) interspersed with visual and functional analyzes. The tested worst case devices withstand 100 cycles of use without compromising their functionalities, validating the recommendations provided in the draft Instructions for Use.

Biocompatibility Testing

A biological assessment was performed according to ISO 10993-1 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" and to the FDA Guidance document "*Use of International Standard ISO 10993- 1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff*". Representative samples of the subject devices were subjected to the chemical characterization (ISO 10993-18) and cytotoxicity testing (ISO 10993-5).

The subject devices are similar in material and manufacturing processes to the primary predicate and reference devices, therefore, no new issues regarding biocompatibility were raised and no additional biocompatibility testing was required.

In summary, the nonclinical testing provided for the subject device met the acceptance criteria for each standard and test methodology used to evaluate the subject device as shown in the table above. No clinical data was included in this submission.

Conclusion

The conclusions drawn from the non-clinical tests submitted in this premarket notification demonstrate that the proposed devices are as safe, as effective, and performs as well as or better than the predicate device, K203618, Neodent EasyGuide Kit Cases.