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

July 7, 2023

Re: K230804
Trade/Device Name: Complement Kit Cases
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: June 5, 2023
Received: June 5, 2023

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.07.07 12:15:20 -04'00'

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230804

Device Name
Complement Kit Cases

Indications for Use *(Describe)*

Indications for Use for Neodent Complement Kit Cases:
Neodent Instrument 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:
Dynamic Air Removal (pre-vacuum)- Exposure at 132 °C for 4 minutes, 30-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 Complement Case and the associated instruments is 75,7 g. The weight of the empty Kit Case is 53.62 grams.
Neodent Instrument Kit Cases should not be stacked during sterilization.

Indications for Use for Nuvo Complement Kit Cases:
Nuvo™ Instrument 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. Nuvo™ Instrument Kit Cases are intended to allow sterilization of the enclosed medical devices. Nuvo™ 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:
Dynamic Air Removal (pre-vacuum)- Exposure at 132 °C for 4 minutes, 30-minute dry time.
Gravity displacement - Exposure at 132 °C for 15 minutes, 20-minute dry time.
Nuvo™ Instrument Kit Cases are intended for sterilization of non-porous loads. The combined weight of the Complement Case and the associated instruments is 75.7 g. The weight of the empty Kit Case is 52.72 grams.
Nuvo™ 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	7 July 2023
Preparer / Alternate Contact	Bárbara Uzae Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA E-mail: barbara.uzae@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Complement 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	K182865 – Neodent Instrument Kit Cases, JJGC Indústria e Comércio de Materiais Dentários S.A
Classification Name	Sterilization Wrap Containers, Trays, Cassettes & Other
Classification Regulation	21 CFR 880.6850, Class II
Product Code	KCT

INDICATIONS FOR USE

Indications for Use for Neodent Complement Kit Cases:
Neodent Instrument 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:
Dynamic Air Removal (pre-vacuum)- Exposure at 132 °C for 4 minutes, 30-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 Complement Case and the associated instruments is 75.7 g. The weight of the empty Kit Case is 53.62 grams.
Neodent Instrument Kit Cases should not be stacked during sterilization.

Indications for Use for Nuvo Complement Kit Cases:
Nuvo™ Instrument 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. Nuvo™ Instrument Kit Cases are intended to allow sterilization of the enclosed medical devices. Nuvo™ 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:
Dynamic Air Removal (pre-vacuum)- Exposure at 132 °C for 4 minutes, 30-minute dry time. Gravity displacement - Exposure at 132 °C for 15 minutes, 20-minute dry time.
Nuvo™ Instrument Kit Cases are intended for sterilization of non-porous loads. The combined weight of the Complement Case and the associated instruments is 75.7 g. The weight of the empty Kit Case is 52.72 grams.
Nuvo™ Instrument Kit Cases should not be stacked during sterilization.

SUBJECT DEVICE DESCRIPTION
The subject devices Complement Kit Cases consist of a storage case for Neodent and Nuvo instruments set. They are made of autoclavable polymer, the case has silicone holders to store and hold each instrument securely during sanitization, sterilization and surgical procedures. The case can be equipped according to the procedure.

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)
110.335	Complement Case (model 2)	81 x 67 x 60 mm	212.304 (Lid)	50 x 80 x 30 mm
			212.087 (Base)	59 x 81 x 35 mm
CD1099002	Complement Case (model 2)	81 x 67 x 60 mm	702989 (Lid)	58 x 80 x 30 mm
			212.087 (Base)	59 x 81 x 35 mm

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

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	COMPARISON
	Complement Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	**K182865** Neodent Instrument Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	
Indications for Use Statement	**Indications for Use for Neodent Complement Kit Cases:** Neodent Instrument 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: Dynamic Air Removal (pre-vacuum) - Exposure at 132 °C for 4 minutes, 30-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 Complement Case and the associated instruments is 75.7 g. The weight of the empty Kit Case is 53.62 grams. Neodent Instrument Kit Cases should not be stacked during sterilization. **Indications for Use for Nuvo Complement Kit Cases:** Nuvo™ Instrument 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. Nuvo™ Instrument Kit Cases are intended to allow sterilization of the enclosed medical devices. Nuvo™ 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: Dynamic Air Removal (pre-vacuum)- Exposure at 132 °C for 4 minutes, 30-minute dry time. Gravity displacement - Exposure at 132 °C for 15 minutes, 20-minute dry time. Nuvo™ Instrument Kit Cases are intended for sterilization of non-porous loads. The combined weight of the Complement Case and the associated instruments is 75.7 g. The weight of the empty Kit Case is 52.72 grams. Nuvo™ Instrument Kit Cases should not be stacked during sterilization.	**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 GM Prosthetic Kit Case maximum load weight is 50 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.	**Equivalent** Although the language is slightly different , the indications for use are equivalent. Both subject and predicate devices are intended to allow organization and sterilization of the enclosed medical devices. The difference in the text is specific due to the weight of each device in their maximum load configuration.

	SUBJECT DEVICE	**PRIMARY PREDICATE DEVICE**	**COMPARISON**
	Complement Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	**K182865** Neodent Instrument Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	
Indications for Use Statement		**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.	**Equivalent** Although the language is slightly different , the indications for use are equivalent. Both subject and predicate devices are intended to allow organization and sterilization of the enclosed medical devices. The difference in the text is specific due to the weight of each device in their maximum load configuration.
Intended Use	This product is intended to hold and store surgical and/or prosthetic instruments during their use and sterilization. Use of this product streamlines the storage and organization od instruments during and after the dental procedure.	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.	**Equivalent** Subject and predicate device are intended to safe storage surgical instruments and provide support during sterilization.
Device Classification	Class II	Class II	**Identical**
Classification Name	Sterilization Wrap Containers, Trays, Cassettes & Other	Sterilization Wrap Containers, Trays, Cassettes & Other	**Identical**
Product Code	NHA	NHA	**Identical**
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. Retention fixtures of titanium alloy.	**Equivalent** Subject and primary predicate devices have the same materials.
Perforated	Yes; allows moist heat (steam) penetration to achieve sterilization.	Yes; allows moist heat (steam) penetration to achieve sterilization	**Identical**
Reusable	Yes	Yes	**Identical**

	SUBJECT DEVICE	**PRIMARY PREDICATE DEVICE**	**COMPARISON**
	Complement Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	**K182865** Neodent Instrument Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	
Overall dimensions	110.335: 81 L x 67 W x 60 H, mm CD1099002: 81 L x 67 W x 60 H, mm	For 110.295: 195 L x 90 W x 44 H, mm For 110.294: 195 L x 90 W x 54 H, mm For 110.287: 264 L x 163 W x 54 H, mm For 110.296: 264 L x 163 W x 58 H, mm	**Equivalent** Subject Kit Cases have overall dimensions within the overall dimensions of the predicate devices, not representing a critical case. The difference between them does not compromise safety and efficacy as is better discussed along this submission.
Volume to Vent Ratio	110.335: 27.4 cm^3/ cm^2 (10.78 in^3/ in^2) CD1099002: 27.4 cm^3/ cm^2 (10.78 in^3/ in^2)	110.296: 107.5 cm^3 / cm^2 (42.32 in^3/ in^2) 110.287**:** 98.04 cm^3 / cm^2 (38.60 in^3/ in^2) 110.294: 52.3 cm^3 / cm^2 (20.59 in^3/ in^2) 110.295: 40.5 cm^3 / cm^2 (15.94 in^3/ in^2)	**Equivalent** The primary predicate devices have volume to vent ratio bigger than the subject devices. Thus, the subject devices do not represent criticality for sterilization procedure and the difference between them and predicate devices does not compromise safety and efficacy, as is proved by the presented sterilization validation.
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.	**Identical**
Sterilization Method	Moist heat (steam) to a SAL of 10^{-6}	Moist heat (steam) to a SAL of 10^{-6}	**Identical**
Cycles	Gravity displacement Dynamic Air Removal (pre-vacuum)	Gravity displacement Gravity displacement (pre-vacuum)	**Identical**

	SUBJECT DEVICE	**PRIMARY PREDICATE DEVICE**	**COMPARISON**
	Complement Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	**K182865** Neodent Instrument Kit Cases JJGC Indústria e Comércio de Materiais Dentários S.A.	
Parameters	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: 30 minutes.	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.	**Equivalent** The subject devices have the same cycle parameters already cleared for the predicate devices.
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 devices cleared per K182865 have similar intended use and equivalent Indications for Use Statements. Both are reusable rigid containers used to organize and protect dental surgical instruments that are sterilized by the healthcare provider. The subject device and 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 primary predicate device 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 equivalent to the range of overall dimensions cleared for the predicate devices. The subject device and the primary predicate device are manufactured from materials with a history biocompatibility and clinical use for the cleared indications. The subject device and the predicate devices are to be used according to the validated labeling (sterilization processes and cycles).

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
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

<u>Manual cleaning and sterilization validation</u>

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 validation

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 passed the visual and functional inspections, validating the recommendations provided in the draft Instructions for Use.

Biocompatibility

A biological assessment was performed according to ISO 10993-1:2018 "*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"*. No new issues of biocompatibility are raised for the subject devices and no additional biocompatibility testing was required.

CONCLUSION

The subject devices and the primary predicate device have equivalent instructions for use, intended use, design, technological characteristics and overall dimensions. They also present same materials, sterilization method and sterile barrier. Based on that, it is possible to assess that the new devices do not constitute a new critical case, do not raise the risks and present performance equivalent to the presented predicate. The conclusions drawn from the non-clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the predicate device K182865.