December 13, 2023

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: K231803
Trade/Device Name: Neodent Implant System - Zirconia Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 13, 2023
Received: November 13, 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 (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,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K231803

Device Name
Neodent Implant System - Zirconia Implant System

Indications for Use *(Describe)*

Indications for Use for Zirconia Healing Abutment:
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.
Healing,

Indications for Use for Zirconia Base:
The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations, such as copings or crowns. It may be used for cement- or screw-retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for CR Abutment for Zirconia Implant System:
The CR Abutment is an abutment placed over Neodent Zirconia Implants in order to provide support for prosthetic restorations, such as copings or crowns. It may be used for single unit restorations that are cement-retained in esthetical areas over implants installed in maxilla or mandible.

Indications for Use for PEEK CR Abutment for Zirconia Implant System:
The PEEK CR Abutment is indicated to be used on Neodent Implants to provide support for prosthetic structures for up to 6 months. They can be used in single- or two-stage procedures and they are intended to be placed out of occlusion.

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

Neodent Implant System – Zirconia Implant System

510(k) Summary K231803

510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: JJGC Indústria e Comércio de Materiais Dentários AS (dba Neodent) Av. Juscelino Kubitschek de Oliveira, 3291 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 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
Date of Submission:	December 13, 2023

Name of the Device

Trade Names:	Neodent Implant System – Zirconia Implant System
Common Name:	Endosseous dental implant abutment
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630, Class II
Device Classification:	II
Product Code(s):	NHA
Classification Panel:	Dental Products Panel

Predicate Device and Reference Devices

Primary Predicate:

- *K201491 - Neodent Implant System - Zirconia Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*

Reference Devices:

- *K210336 – Neodent Implant System – Zirconia Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*
- *K202282 – Neodent Implant System – Zirconia Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*
- *K163194 – Neodent Implant System – GM Line (JJGC Indústria e Comércio de Materiais Dentários S.A)*
- *K180477 - Straumann PURE Ceramic Implant System (Straumann USA, LLC)*
- *K182620 – MRI Compatibility For Existing Neodent Implant System*

Device Description

The Zirconia Abutments subject of this submission are similar to devices already approved in previous submissions of Zirconia Implant System, according to predicate devices described above. This submission intends to expand the portfolio of Zirconia Abutments with new dimensions of gingival height for Zirconia Healing Abutments, Zirconia Bases, CR Abutments for Zirconia and PEEK CR Abutments for Zirconia, to provide more treatment options to the customers. All these abutments have an internal connection with the implants (ZiLock) and the prosthetic platform is identical for all subject devices described in this submission. They are intended for single use and provided sterile via Ethylene Oxide method. The new transmucosal heights are 3.5mm and 4.5mm.

The restorative materials Polycon ae, N!ce and IPS e.max CAD LT were not presented in previous submissions of Zirconia Implant System and are being included in the scope of Zirconia Bases indication.

Intended Use

Zirconia Healing Abutment:

The Zirconia Healing Abutment is used for the maintenance of soft tissues during the osseointegration phase of Neodent Implants to be rehabilitated using the late loading technique. It can be used in the implant placement surgery or in the re-opening surgery (second surgical phase). It is indicated according to the interocclusal space available, existing transmucosal height and three-dimensional position of the implant. Check the compatibility between the prosthetic interfaces chosen. Zirconia Healing Abutments are available only for Zirconia implants, being compatible with corresponding abutments of the same lines.

Zirconia Base:

Zirconia Base consists of a two-piece abutment, where the zirconia base is a pre-manufactured abutment that will be used to support a CAD/CAM-designed superstructure (the second part of the two-piece abutment) that composes the final abutment.

The Zirconia Base is indicated according to the interocclusal space available, existing gingival height and three-dimensional position of the implant. This product can be used in single-unit restorations. This product is compatible only with the Neodent Zirconia Implant System. For the design of the customized prosthetic structure, it is intended to be used with the Zirconia Base library on Dental Wings and 3Shape systems or softwares. For manufacturing, the design data is intended to be sent to the validated milling center.

CR Abutment for Zirconia Implant System:

The CR Abutment for Zirconia Implants is a device indicated for single-unit cement-retained prosthesis over Zirconia Implants, installed in maxilla or mandible. It is supplied along with a screw for fixating the abutment over the implant. Neodent Prosthetic Components are used as intermediaries between the implant and the prosthesis, planned according to each case, respecting the prosthetic interfaces, aiming at aesthetics and function. This product is indicated according to the available interocclusal space, existing gingival height and three-dimensional position of the implant. The CR Abutments for Zirconia Implants are available only for the Neodent Zirconia Implant System interface (Zi-Lock), being compatible with corresponding implants from the same line.

PEEK CR Abutment for Zirconia Implant System:

The PEEK CR Abutment for Zirconia is a device indicated for use in the production of a single-unit provisional prosthesis on Zirconia Implants, installed in maxilla or mandible. It is supplied along with a screw for fixating the Abutment over the Implant. This product is indicated according to the available interocclusal space, existing gingival height, and three-dimensional position of the implant. It can be used before the installation of the final abutments to maintain, stabilize, and shape soft tissues (gingiva) during the healing phase. The PEEK Abutments for Zirconia are available only for Zirconia interface, being compatible with corresponding implants from the same line.

Indications for Use

Zirconia Healing Abutment:

The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.

Zirconia Base:

The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations, such as copings or crowns. It may be used for cement- or screw-retained single unit restorations.

All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

CR Abutment for Zirconia Implant System:

The CR Abutment is an abutment placed over Neodent Zirconia Implants in order to provide support for prosthetic restorations, such as copings or crowns. It may be used for single unit restorations that are cement-retained in esthetical areas over implants installed in maxilla or mandible.

PEEK CR Abutment for Zirconia Implant System:

The PEEK CR Abutment is indicated to be used on Neodent Implants to provide support for prosthetic structures for up to 6 months. They can be used in single- or two-stage procedures and they are intended to be placed out of occlusion.

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 and predicate device (Zirconia Healing Abutments)

FEATURE	PROPOSED DEVICE	PRIMARY DEVICE
K Number		K201491
Indications for Use	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single stage or two-stage surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single stage or two-stage surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.
Material	Healing Abutment: Yttrium-stabilized zirconium dioxide (Y-TZP) Screw: Titanium alloy, according to ASTM F136 standard.	Healing Abutment: Yttrium-stabilized zirconium dioxide (Y-TZP) Screw: Titanium alloy, according to ASTM F136 standard.
Implant to Abutment Connection	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)
Diameter	Ø 3.75 and 4.5 mm	Ø 3.75 and 4.5 mm
Gingival Height	3.5 and 4.5 mm	1.5 and 2.5 mm
Sterilization Method	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}

Table 2 – Comparison of subject device and predicate and reference devices (Zirconia Base)

<table>
<tr><th>FEATURE</th><th>PROPOSED DEVICE</th><th>PRIMARY PREDICATE DEVICE</th><th colspan="2">REFERENCE DEVICE</th></tr>
<tr><td>K Number</td><td></td><td>K201491</td><td>K163194</td><td>K180477</td></tr>
<tr><td>Indications for Use</td><td>The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations, such as copings or crowns. It may be used for cement- or screw retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a</td><td>The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations, such as copings or crowns. It may be used for cement- or screw retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated</td><td colspan="2"></td></tr>
<tr><td>Material</td><td>Healing Abutment: Yttrium-stabilized zirconium dioxide (Y-TZP)
Screw: Titanium alloy, according to ASTM F136 standard.</td><td>Healing Abutment: Yttrium-stabilized zirconium dioxide (Y-TZP)
Screw: Titanium alloy, according to ASTM F136 standard.</td><td colspan="2"></td></tr>
<tr><td>Implant to Abutment Connection</td><td>Straight internal connection indexing features (Zilock)</td><td>Straight internal connection indexing features (Zilock)</td><td colspan="2"></td></tr>
<tr><td>Diameter</td><td>Ø 3.75 and 4.5 mm</td><td>Ø 3.75 and 4.5 mm</td><td colspan="2"></td></tr>
<tr><td>Gingival Height</td><td>3.5 and 4.5 mm</td><td>1,5 and 2,5 mm</td><td colspan="2"></td></tr>
<tr><td>Design Workflow</td><td>Zirconia Base library on Dental Wings, Exocad and 3Shape systems or softwares</td><td>Zirconia Base library on Dental Wings, Exocad and 3Shape systems or softwares</td><td colspan="2"></td></tr>
<tr><td>Top Half Material</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness</th><th>Maximum angulation</th></tr>
<tr><td>3M ESPE Lava Plus Zirconia</td><td>0.7 mm</td><td rowspan="5">30°</td></tr>
<tr><td>Zerion LT</td><td>0.4 mm</td></tr>
<tr><td>N!ce</td><td>1.0 mm</td></tr>
<tr><td>Polycon ae*</td><td>0.7 mm</td></tr>
<tr><td>IPS e.max CAD</td><td>0.9 mm</td></tr>
<tr><td colspan="3">*Polycon ae material is only recommended for temporary/provisional prosthetic restorations.</td></tr>
</table>
</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness</th><th>Maximum angulation</th></tr>
<tr><td>3M ESPE Lava Plus Zirconia</td><td>0.7 mm</td><td rowspan="3">30°</td></tr>
<tr><td>Zerion LT</td><td>0.4 mm</td></tr>
<tr><td>Zerion UTML</td><td>0.5 mm</td></tr>
</table>
</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness</th><th>Maximum angulation</th></tr>
<tr><td>IPS e.max CAD</td><td>0.9 mm</td><td>30°</td></tr>
</table>
</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness</th><th>Maximum angulation</th></tr>
<tr><td>N!ce</td><td>-</td><td>30°</td></tr>
<tr><td>Polycon ae</td><td>-</td><td>30°</td></tr>
<tr><td colspan="3">*Polycon ae material is only recommended for temporary/provisional prosthetic restorations.</td></tr>
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FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
K Number		K201491	K163194	K180477
Sterilization Method	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}. If customized on the chairside, must be sterilized before the installation via moist heat (steam), using either gravity or vacuum, with an exposure time of 3 minutes at 132°C (270°F).	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}. If customized on the chairside, must be sterilized before the installation via moist heat (steam), using either gravity or vacuum, with an exposure time of 3 minutes at 132°C (270°F).		

Table 3 – Comparison of subject device and predicate device (Zirconia CR Abutment)

FEATURE	PROPOSED DEVICE	REFERENCE PREDICATE DEVICE
K Number		K202282
Indications for Use	The CR Abutment is an abutment placed over Neodent Zirconia Implants in order to provide support for prosthetic restorations, such as copings or crowns. It may be used for single unit restorations that are cement-retained in esthetical areas over implants installed in maxilla or mandible.	The CR Abutment is an abutment placed over Neodent Zirconia Implants in order to provide support for prosthetic restorations, such as copings or crowns. It may be used for single unit restorations that are cement-retained in esthetical areas over implants installed in maxilla or mandible.
Material	Healing Abutment: Yttrium-stabilized zirconium dioxide (Y-TZP) Screw: Titanium alloy, according to ASTM F136 standard.	Healing Abutment: Yttrium-stabilized zirconium dioxide (Y-TZP) Screw: Titanium alloy, according to ASTM F136 standard.
Implant to Abutment Connection	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)
Design	Angulation: 0 and 17° Plataform: regular and narrow	Angulation: 0 and 17° Plataform: regular and narrow
Gingival Height	3.5 and 4.5 mm	1.5 and 2.5 mm
Sterilization Method	Provided sterile via Ethylene Oxide to an SAL of 10^{-6} If customized on the chairside, must be sterilized before the installation via moist heat (steam), using either gravity or vacuum, with an exposure time of 3 minutes at 132°C (270°F).	Provided sterile via Ethylene Oxide to an SAL of 10^{-6} If customized on the chairside, must be sterilized before the installation via moist heat (steam), using either gravity or vacuum, with an exposure time of 3 minutes at 132°C (270°F).

Table 4 – Comparison of subject device and predicate device (PEEK CR Abutment)

FEATURE	PROPOSED DEVICE	REFERENCE PREDICATE DEVICE
K Number		K210336
Indications for Use	Neodent prosthetic abutments are indicated to be used on Neodent implants to provide support for prosthetic structures for up to 6 months. They can be used in single- or two-stage procedures and they are intended to be placed out of occlusion.	Neodent prosthetic abutments are indicated to be used on Neodent implants to provide support for prosthetic structures for up to 6 months. They can be used in single- or two-stage procedures and they are intended to be placed out of occlusion.
Material	Body and base (implant-to-abutment interface): PEEK (high performance polymer – specific for dental use) Screw: Titanium Alloy (ASTM F136)	Body and base (implant-to-abutment interface): PEEK (high performance polymer – specific for dental use) Screw: Titanium Alloy (ASTM F136)
Implant to Abutment Connection	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)
Design	Cylindrical cementable body with a passing hole to fixate the screw and an anti-rotational prosthetic interface.	Cylindrical cementable body with a passing hole to fixate the screw and an anti-rotational prosthetic interface.
Diameter	Ø 4.0 and 4.5 mm	Ø 4.0 and 4.5 mm
Angulation	Straight only	Straight only
Gingival Height	3.5 and 4.5 mm	1.5 and 2.5 mm
Sterilization Method	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}

Performance Testing

Bench Testing

Assessment regarding dynamic fatigue testing was conducted according to the FDA guidance document "*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*" and ISO 14801 "*Dentistry — Implants — Dynamic loading test for endosseous dental implants*". The results demonstrated the subject devices do not introduce a new worst case compared to the primary predicate and reference devices. In addition to testing on subject device, dynamic fatigue testing was leveraged from the primary predicate (K201491).

Torsion tests were performed to evaluate the strength of the screw supplied with all subject abutments against maximum twisting forces. The results proven that there is an adequate torsion strength according to the installation torque indicated in IFU.

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, Document issued on: June 16, 2016*" for each subject device.

The subject devices are identical 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.

Sterilization Validation and Packaging

The subject devices are provided sterile via Ethylene Oxide (EO) method, validated to a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135:2014, "*Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*". EO sterilization residuals have been verified to be less than the maximum allowable limits as defined in ISO 10993-7 "*Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals*". The packaging and sterilization of the subject device are identical to the packaging and sterilization of the primary predicate devices.

Steam sterilization has been validated according to ISO 17665-1 "*Sterilization of health care products - Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*", using the parameters described in IFU, which are identical to the parameters validated for the primary predicate and reference devices.

The devices will not be marketed as non-pyrogenic. Pyrogenicity information provided is based on FDA Guidance on "*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile*, issued on 21 January 2016." The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on a blood contacting and implanted device.

Conclusion

The documentation submitted in this premarket notification demonstrates the subject devices are substantially equivalent to the primary predicate and reference devices.