December 22, 2020

JJGC Industria e Comercio de Materiais Dentarios S.A.
% Jennifer Jackson
Director of Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K201491
Trade/Device Name: Neodent Implant System - Zirconia Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 20, 2020
Received: November 23, 2020

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,

Andrew Steen
Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201491

Device Name
Neodent Implant System - Zirconia Implant System

Indications for Use *(Describe)*
Indications for Use for Zirconia Implants, Cover Screw and 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 singlestage 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201491

Device Name
Neodent Implant System - Zirconia Implant System

Indications for Use *(Describe)*
Indications for Use for Zirconia Bases:

The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for patient-specific 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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	21/December/2020
Preparer / Alternate Contact	Mariana Soares 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 – Zirconia Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Name	Endosseous dental implant
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE / NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K101945 – Neodent Implant System – CM Line, JJGC Indústria e Comércio de Materiais Dentários S.A

Reference Devices	K150367 - Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A K132881 - Z5c, Z-Systems AG K153624 - Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A K180477 – Straumann PURE Ceramic Implant System, Institut Straumann AG K182620 - MRI Compatibility For Existing Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A K192893 - Straumann® Ceramic Healing Abutments, Institut Straumann AG

INDICATIONS FOR USE

Indications for Use for Zirconia Implants, Cover Screw, and Healing Abutments:

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 appropriate occlusal loading. Multiple teeth applications can be rigidly splinted.

Indications for Use for Zirconia Bases:

The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for patient-specific 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.

SUBJECT DEVICE DESCRIPTIONS

- Intended for single use;
- Zirconia implants provided sterile via Ethylene Oxide; Zirconia Base abutments are provided sterile but require end user sterilization via moist heat following cementation of the restoration and before use
- All devices of Zirconia Implant System are manufactured of Y-TZP (Yttrium-stabilized zirconium dioxide), except for the Zirconia Implant Cover Screw and the Basal Screw, which is manufactured of titanium alloy according to ASTM F136 standard;
- ZiLock prosthetic interface with internal indexer;
- Apically tapered implant with trapezoidal thread profile;
- Implant provided with sand-blasted, acid etched surface finish to facilitate osseointegration.
- The final finished Zirconia Base abutments are two-piece abutments composed of a zirconia base bottom-half bonded to a CAD-CAM zirconia top-half.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLES

Table 1. Technological Characteristic Comparison Table - Zirconia Implants, Cover Screws, and Healing Abutments

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	K201491 Neodent Implant System - Zirconia Implant System - Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System Alvim Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K180477** Straumann PURE Ceramic Implant System Implants Institut Straumann AG	**Equivalence Discussion**
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 appropriate 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 procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple teeth applications can be rigidly splinted	Straumann PURE Ceramic Implant: The Straumann PURE Ceramic Implant is indicated for the restoration of single-tooth gaps and in edentulous or partially edentulous jaws. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. Closure and healing caps: Closure and Healing caps are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Closure and Healing caps should be used only with suitable implant connections. Do not use healing components for longer than 6 months. Temporary Abutments: The provisional components are intended to serve as a base for temporary crown or bridge restoration out of occlusion for the Straumann® PURE Ceramic Implant System. The Straumann® Temporary Abutment VITA CAD-Temp® for the Straumann® PURE Ceramic Implant is indicated for temporary usage of up to 180 days. CI RD Straumann PUREbase Abutments:	**Identical** The Indications for Use of the subject devices are the same as for the primary predicate devices.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	K201491 Neodent Implant System - Zirconia Implant System - Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System Alvim Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K180477** Straumann PURE Ceramic Implant System Implants Institut Straumann AG	**Equivalence Discussion**
			CI RD Straumann PUREbase abutment is a titanium base placed onto Straumann ceramic dental implants to provide support for customized prosthetic restorations and is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.	
Implant-Abutment interface	Straight internal connection indexing features (Zilock)	CM Morse Taper	Straight internal connection indexing features (RD)	**Equivalent** Subject devices and reference devices present internal connection and are equipped with a rotational lock and an inner thread for fixation of the temporary components and final abutments.
Design	Apically Tapered format Trapezoidal threads profile Bone compression capacity during installation	Apically Tapered format Trapezoidal threads profile	Straight cylindrical implant body	**Equivalent** The subject devices have the same apically-tapered shape and trapezoidal thread form as the primary predicate device.
Reusable	No	No	No	**Identical** The subject devices and the primary predicate devices are indicated for single use.
Length (mm)	8; 10; 11.5; 13	8; 10; 11.5; 13; 16	8; 10; 12; 14	**Equivalent** Range of lengths for subject devices is within the range of lengths for the primary predicate devices.
Diameter (Ø)	4.3 mm	3.5; 4.3; 5.0 mm	Endosteal 4.1 mm	**Equivalent**

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	K201491 Neodent Implant System - Zirconia Implant System - Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System Alvim Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K180477** Straumann PURE Ceramic Implant System Implants Institut Straumann AG	**Equivalence Discussion**
(mm)			Platform 4.8 mm	Diameter of subject devices is within the range of diameters for the primary predicate devices.
Material	Yttrium-stabilized zirconium dioxide (Y-TZP).	Commercially pure titanium (Grade 4)	Yttrium-stabilized zirconium dioxide (Y-TZP).	**Equivalent** The subject devices have the same material of construction as the identified reference devices.
Sterilization Method	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	Provided sterile via Gamma irradiation to an SAL of $1x10^{-6}$	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	**Equivalent** The subject devices and the primary predicate devices are provided in sterile condition to an SAL of 1×10^{-6}. The subject devices use the same sterilization method as for the reference devices.

Table 2. Technological Characteristic Comparison Table - Zirconia Bases

	SUBJECT DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	
	K201491 Neodent Implant System - Zirconia Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K180477** Straumann PURE Ceramic Implant System PUREbase Abutments Institut Straumann AG	**K150367** Neodent Implant System Titanium Base Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K132881** Z5c Z-Systems AG	**Equivalence Discussion**
Indications for Use	The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for patient-specific 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.	Straumann PURE Ceramic Implant: The Straumann PURE Ceramic Implant is indicated for the restoration of single-tooth gaps and in edentulous or partially edentulous jaws. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. Closure and healing caps: Closure and Healing caps are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Closure and Healing caps should be used only with suitable implant connections. Do not use healing components for longer than 6 months. Temporary Abutments: The provisional components are intended to serve as a base for temporary crown or bridge restoration out of occlusion for the Straumann® PURE Ceramic Implant System. The Straumann® Temporary Abutment VITA CAD-Temp® for the Straumann® PURE Ceramic Implant is indicated for temporary usage of up to 180 days. CI RD Straumann PUREbase Abutments: CI RD Straumann PUREbase abutment is a titanium base placed onto Straumann ceramic dental implants to provide support for customized prosthetic restorations and is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.	Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement- or screw-retained single or multi-unit restorations single. All digitally designed copings and/or crowns to be used with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. The GM Titanium Base for Bridge is indicated for cement or screw-retained multi-unit restorations	Z5c implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. Z5c implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them. Z5c implants are intended for delayed loading.	**Equivalent** The Indications for the subject devices are equivalent to reference devices (K150367). Although the words are different, the content of the indications for use are similar. The primary predicate covers the indications for use of the reference devices. The indications for use of the subject devices are contained within the indications for use of the primary predicate devices.

	SUBJECT DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	
	K201491 Neodent Implant System - Zirconia Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K180477** Straumann PURE Ceramic Implant System PUREbase Abutments Institut Straumann AG	**K150367** Neodent Implant System Titanium Base Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K132881** Z5c Z-Systems AG	**Equivalence Discussion**
Implant-Abutment interface	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (RD)	CM Morse Taper	--	**Equivalent** Subject devices and reference devices (K180477) present internal connection and are equipped with a rotational lock and an inner thread for fixation of the temporary components and final abutments.
Maximum Angulation of Prosthetic Structure	30˚	30˚	30˚	15°	**Identical** The maximum restorative angulation for the subject and reference devices (K180477 and K150367) is the same.
Gingival height (mm)	1.5 – 2.5 mm	--	0.8 - 4.5 mm	---	**Equivalent** The range of gingival heights for the subject devices is within the range of gingival heights of the reference devices (K150367).
Reusable	No	No	No	No	**Identical** The subject devices and reference devices are indicated for single use.

	SUBJECT DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	
	K201491 Neodent Implant System - Zirconia Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K180477** Straumann PURE Ceramic Implant System PUREbase Abutments Institut Straumann AG	**K150367** Neodent Implant System Titanium Base Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K132881** Z5c Z-Systems AG	**Equivalence Discussion**
Abutment Material	Zirconia Base: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium alloy Screw according to ASTM F136 standard.	Ti-6Al-7Nb	Titanium alloy according to ASTM F136 standard.	Yttrium-stabilized zirconium dioxide (Y-TZP).	**Equivalent** The subject devices and the reference devices (K132881) have the same material of construction.
Restoration Material	zerion LT zerion UTML 3M LavaPlus Zirconia	polycon ae (temporary) zerion LT/HT (permanent) zerion ML/UTML (permanent) IPS e.max CAD (permanent) n!ce (permanent)	Zirconia	--	**Equivalent** The subject devices and the reference devices have equivalent materials of construction.
Design workflow	Zirconia Base library on Dental Wings and 3Shape systems or software	CAD with CARES Visual v.11	CARES Visual, Dental Wings and 3shape software	--	**Equivalent** The subject and reference devices are indicated for use within a digital restorative workflow. The same CAD software can be used to design the prosthetic portion of the devices.

	SUBJECT DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	
	K201491 Neodent Implant System - Zirconia Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K180477** Straumann PURE Ceramic Implant System PUREbase Abutments Institut Straumann AG	**K150367** Neodent Implant System Titanium Base Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K132881** Z5c Z-Systems AG	**Equivalence Discussion**
Manufacturing workflow	Straumann Milling Center	Straumann Milling Center	Straumann Milling Center	--	**Identical** The prosthetic portion of the assembly for the subject devices and reference devices (K180477 and K150367) are indicated for fabrication in a registered medical device manufacturing facility.
Sterilization Method	Provided sterile via Ethylene Oxide to an SAL of 10^{-6} End user sterilized via moist heat following cementation of coping and before use	Non-sterile End user sterilized via moist heat following cementation of coping and before use	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	--	**Identical** The subject devices and the reference devices (K150367) are provided in sterile condition to an SAL of 1×10^{-6}. The subject devices use the same sterilization method as for the reference devices.

Table 3. Technological Characteristic Comparison Table – Zirconia Implant Cover Screw

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System - Zirconia Implant System Cover Screws JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System Cover Screws JJGC Indústria e Comércio de Materiais Dentários S.A.	
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 appropriate 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 procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	**Equivalent** The Indications for the subject devices are included within the scope on Indications for the primary predicate devices.
Reusable	No	No	**Identical** The subject devices and the primary predicate devices are both intended for single use.
Material	Titanium alloy according to ASTM F136 standard.	Titanium alloy according to ASTM F136 standard.	**Identical** The subject devices have the same material of construction as the primary predicate devices.
Sterilization Method	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	**Identical** The subject devices have the same sterilization method and same SAL as the primary predicate devices.

Table 4. Technological Characteristic Comparison Table - Zirconia Implant Healing Abutments

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	Neodent Implant System - Zirconia Implant System Healing Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System Healing Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K192893** Straumann Ceramic Healing Abutments Healing Abutments Institut Straumann AG.	**Equivalence Discussion**
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 appropriate 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 procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple teeth applications can be rigidly splinted	Straumann® Ceramic Healing abutments are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Healing abutments should be used only with suitable implant connections. The healing components are intended to be used up to 6 months.	**Equivalent** The Indications for the subject devices are included within the scope on Indications for the primary predicate devices.
Implant-Abutment interface	Straight internal connection indexing features (Zilock)	CM	Straight internal connection indexing features (RD)	**Equivalent** Subject devices and reference devices (K192893) present internal connection and are equipped with a rotational lock and an inner thread for fixation of the temporary components and final abutments.
Reusable	No	No	No	**Identical** The subject and primary predicate devices are indicated for single use.
Material	Healing Abutment: Yttrium-stabilized zirconium dioxide (Y-TZP) Screw: Titanium alloy Screw according to ASTM F136 standard.	Healing Abutment and Screw: Titanium alloy according to ASTM F136 standard.	Healing Abutment: Yttrium-stabilized zirconium dioxide (Y-TZP) Screw: Titanium alloy (Ti-6Al-7Nb or TAN)	**Equivalent** The materials of construction for the subject devices are equivalent to those of the reference devices.
Diameter (Ø) (mm)	3.75 and 4.5	3.3 and 4.5 mm	NC: 3.6 and 4.8 mm RC: 4.5, 5.0, 6.0, and 6.5 mm	**Equivalent** The range of diameters of the subject devices are within the range of diameters for the primary predicate devices.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	Neodent Implant System - Zirconia Implant System Healing Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System Healing Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K192893** Straumann Ceramic Healing Abutments Healing Abutments Institut Straumann AG.	**Equivalence Discussion**
Gingival height (mm)	1.5 – 2.5 mm	0.8, 1.5, 2.5, 3.5, 4.5, 5.5, 6.5	NC: 2.0, 3.5, and 5.0 mm RC: 2.0, 4.0, and 6.0 mm	**Equivalent** The range of gingival heights of the subject devices are within the range of gingival heights for the primary predicate devices.
Sterilization	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	Provided sterile via Ethylene Oxide to an SAL of 10-6	**Identical** The subject devices have the same sterilization method and same SAL as the primary predicate devices.

The subject implants have identical indications for use and an equivalent range of lengths and diameter as the primary predicate devices, being within the range of lengths and diameter of the predicate devices.

Subject and predicate devices have implant-to-abutment interfaces with internal indexing. Both present sand-blast and acid-etch surface finishes and same sterile barrier system. The subject implants have the identical surface modification as the reference device (K180477). The subject implants have equivalent materials and sterilization method as the reference device (K180477).

The subject Base abutment have the same indications for use and an equivalent range of gingival height as the primary predicate devices, being within the range of gingival height of the predicate devices. Both, subject devices and primary predicate devices, present the same maximum angulation and sterilization method. The subject bases are made of the same material as the reference devices (K132881).

The subject Cover screws have the same indications for use, same sterilization method, similar design and are made of the same material as the primary predicate devices (K101945).

The subject Healing Abutments have the same indications for use and an equivalent range of gingival height and diameter as the primary predicate devices, being within the range of gingival height and diameter of the predicate devices. They also present the same sterilization method. The subject devices and reference devices are made of the same material (K192893).

Overall, the subject devices are equivalent to the predicate devices as follows:

- same intended use,
- same operating principle,
- incorporate the same basic design,
- incorporate the same materials, and
- have same packaging and are sterilized using the same materials and processes

PERFORMANCE DATA

Biocompatibility

Representative samples of each of the subject devices was subjected to the following:

- Biocompatibility sample preparation was made according to ISO 10993-12.
- Biological Safety Assessment guided by ISO 10993-1,
- Cytotoxicity testing was performed per ISO 10993-5 and
- Chemical characterization was performed per ISO 10993-18.

Mechanical testing

Dynamic fatigue test per ISO 14801 was performed to determine the fatigue strength for the dental implant system, according to FDA Guidance. The tested subject devices exhibit a level of performance equivalent to that reviewed for the predicate devices.

The wear assessment of the Titanium/Ceramic contacting pieces was done before and after the fatigue test. The data produced concluded of comparable behavior of the subject device to the reference devices in terms of wear on the implant-to-abutment connection.

Torsion Test was performed to evaluate the Zirconia Implant System under static torsional loading.
Insertion test was performed to evaluate the insertion torque of the Zirconia Implant System when inserted into sawbones material representing bone type I, II, III and IV.

Sterilization validation

The subject devices are sterilized by Ethylene Oxide, according to ISO 11135-1 via the over-kill method.
The residuals from ethylene oxide sterilization are according to ISO 10993-7
The method achieved a Sterility Assurance Level of $1x10^{-6}$.
The Subject devices are not represented to be “pyrogen free”.

MRI Testing

The MRI Testing was done according to the documents presented on K182620

Shelf Life

The Shelf Life of the Zirconia Implant System is 5 years.
The packaging assessment is guided according to ISO 11607-1 and maintenance of the sterile barrier and the integrity of the sealing after 5 years of Accelerated Aging were confirmed by Dye Penetration, Sealing Strength and Bubble Test.

CONCLUSION

The subject devices and the primary predicate and reference devices have equivalent intended use, design and technological characteristics. Equivalent range of overall dimensions and sterilization method. The data included in this submission demonstrate that the subject devices are substantially equivalent to the predicate devices.