September 6, 2022

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: K220251
Trade/Device Name: Neodent Implant System - GM Narrow Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 4, 2022
Received: August 9, 2022

Dear Jennifer Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K220251

Device Name
Neodent Implant System - GM Narrow Implant System

Indications for Use *(Describe)*
IIndications for Use for Helix NGM Implants:
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. The Implant Narrow GM is indicated to replace upper lateral incisors, lower incisors or for retaining overdenture prostheses.

Indications for Conventional 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 procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Indications for Use for NGM Exact Temporary Abutments:
Prosthetic component to be installed in the Narrow GM Implant, providing support for prosthetic structures. Indicated for temporary restorations with unitary structures, screwed, on implants installed in the maxilla or mandible. Temporary Abutments Narrow GM have a maximum duration of usage of 180 days.

Indications for NGM Exact Titanium Bases:
Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations as copings and crowns. It is indicated for cemented or screw mounted single-cemented applications on implants installed on the maxilla or mandible. All digitally designed copings and/or crowns to be used with the Titanium 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.

K220251
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 Sr. Director of Regulatory Affairs and Quality, Straumann USA E-mail: jennifer.jackson@straumann.com Telephone (978) 747-2509
Date Prepared	06/Sep/2022
Preparer / Alternate Contact	Mariana Hartmann Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA E-mail: mariana.hartmann@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Neodent Implant System – GM Narrow Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Name	Implant, Endosseous, Root-Form Endosseous dental implant abutment
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	K123022, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A

Reference Predicate Devices	K162890 - Straumann Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments - Straumann USA, LLC K203309 – NUVO CF Implant Line, JJGC Indústria e Comércio de Materiais Dentários S.A K182620 - MRI Compatibility For Existing Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A

INDICATIONS FOR USE

Indications for Use for Helix NGM Implants:
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. The Implant Narrow GM is indicated to replace upper lateral incisors, lower incisors or for retaining overdenture prostheses.

Indications for Conventional 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 procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Indications for Use for NGM Exact Temporary Abutments:
Prosthetic component to be installed in the Narrow GM Implant, providing support for prosthetic structures. Indicated for temporary restorations with unitary structures, screwed, on implants installed in the maxilla or mandible. Temporary Abutments Narrow GM have a maximum duration of usage of 180 days.

Indications for NGM Exact Titanium Bases:
Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations as copings and crowns. It is indicated for cemented or screw mounted single-cemented applications on implants installed on the maxilla or mandible. All digitally designed copings and/or crowns to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

SUBJECT DEVICE DESCRIPTIONS

- All the subject devices are intended for single use;
- The subject implants are provided sterile via gamma irradiation and the subject abutments are provided sterile via Ethylene Oxide to an SAL of $1x10^{-6}$;
- The subject implants are manufactured of Commercially Pure Titanium (Grade 4) and the subject abutments are manufactured of Titanium alloy Ti-6Al-4V ELI (ASTM F136),
- The subject implants present a Grand Morse prosthetic interface with internal indexer; cylindrical shape with double threads; cervical diameter equal to the implant body diameter (2.9 mm)

- The implants are provided in two different surfaces: Neoporos: Sand blasted and acid etched, and Acqua: Hydrophilic surface aggregated to the rough surface obtained by double treatment: abrasive blasting and acid subtraction.

SUBSTANTIAL EQUIVALENCE COMPARISON TABLES

The Substantial Equivalence Comparison tables are provided on the pages that follow below.

Table 1: Substantial Equivalence Comparison – Indication for Use Statements - Helix NGM Implants and Conventional and Temporary Abutments

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATE DEVICE
	Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K123022** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K162890** Straumann Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments Straumann USA, LLC
Indications for Use Statement	Indications for Use for Helix NGM Implants: 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. The Implant Narrow GM is indicated to replace upper lateral incisors, lower incisors or for retaining overdenture prostheses. Indications for Use for Conventional 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 procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Indications for Use for NGM Exact Temporary Abutments: Prosthetic component to be installed in the Narrow GM Implant, providing support for prosthetic structures. Indicated for temporary restorations with unitary structures, screwed, on implants installed in the maxilla or mandible. Temporary Abutments Narrow GM have a maximum duration of usage of 180 days. Indications for Use for NGM Exact Titanium Bases: Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations as copings and crowns. It is indicated	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. Titamax WS implant is indicated for a delayed loading protocol. The Facility implant is indicated to replace upper lateral incisors, lower incisors or for retaining overdenture prostheses.	Straumann® Bone Level Tapered Implants Ø2.9 mm are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and aesthetic oral rehabilitation of patients with missing teeth. Straumann® Bone Level Tapered Implants Ø2.9 mm can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth or multiple-tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding components (abutments). The Straumann® Bone Level Tapered Implants Ø2.9 mm are indicated for reconstruction of missing incisors in the lower jaw and lateral incisors in the upper jaw. Straumann® Closure Caps and Healing Abutments are indicated to be placed in the dental implant after placement in the patient's jaw to protect the inner configuration of the implant and to form, maintain and stabilize the soft tissue during the healing process. Closure Caps and Healing Abutments should be used only with the corresponding implant connection. Straumann® SC Temporary Abutments are indicated for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. Straumann® SC Temporary Abutments have a maximum duration of usage of 180 days. Straumann® SC Variobase® abutments are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented on the Straumann® SC Variobase® prosthetic

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATE DEVICE
	Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K123022** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K162890** Straumann Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments Straumann USA, LLC
	for cemented or screw mounted single-cemented applications on implants installed on the maxilla or mandible. All digitally designed copings and/or crowns to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.		components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. 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. Straumann® SC CARES® abutments are indicated for single-tooth replacements and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained.

Table 2: Substantial Equivalence Comparison – Indication for Use Statements - Titanium Bases

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATE DEVICE
	Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K203309** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K162890** Straumann Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments Straumann USA, LLC
Indications for Use Statement	Indications for Use for NGM Exact Titanium Bases: Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations as copings and crowns. It is indicated for cemented or screw mounted single-cemented applications on implants installed on the maxilla or mandible. All digitally designed copings and/or crowns to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	CF Titanium Base for Crown is a titanium abutment placed onto dental implants to provide support for customized prosthetic restorations, as copings or crowns. It is indicated for single-unit restorations, cement-retained or screw-retained in aesthetic areas on implants installed in the maxilla or mandible. All digitally designed copings and/or crowns to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	Straumann® SC Variobase® abutments are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented on the Straumann® SC Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. 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.

Equivalence Discussion about Indications for Use

Implants

The scope of the Indications for Use Statement for the subject Implants (K220251) are identical to the corresponding section of the Indications for Use Statement of the Facility Implant of primary predicate devices (K123022) and similar to the reference predicate devices (K162890).

SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
	K123022	K162890
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. The Implant Narrow GM is indicated to replace upper lateral incisors, lower incisors or for retaining overdenture prostheses.	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. Titamax WS implant is indicated for a delayed loading protocol. The Facility implant is indicated to replace upper lateral incisors, lower incisors or for retaining overdenture prostheses.	Straumann® Bone Level Tapered Implants Ø2.9 mm are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and aesthetic oral rehabilitation of patients with missing teeth. Straumann® Bone Level Tapered Implants Ø2.9 mm can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth or multiple-tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding components (abutments). The Straumann® Bone Level Tapered Implants Ø2.9 mm are indicated for reconstruction of missing incisors in the lower jaw and lateral incisors in the upper jaw.

Conventional and Temporary Abutments

The indications for use of the Conventional Abutments is the same for the subject devices and primary predicate device (K123022). Regarding the Temporary Abutments, although the wording is slightly different, the indications for use are the same (K162890).

SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
	K123022	K162890
Conventional 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 procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. **Temporary Abutments:** Prosthetic component to be installed in the Narrow GM Implant, providing support for prosthetic structures. Indicated for temporary restorations with unitary structures, screwed, on implants installed in the maxilla or mandible. Temporary Abutments Narrow GM have a maximum duration of usage of 180 days.	**Conventional 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 procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	**Temporary Abutments:** Straumann® SC Temporary Abutments are indicated for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. Straumann® SC Temporary Abutments have a maximum duration of usage of 180 days.

Titanium Bases Abutments

The Indications for Use Statement for the subject device are equivalent to the corresponding section of the Indications for Use Statement of K203309 and K162890. Although the wording is slightly different, the Indications for the subject devices are included within the scope on Indications for the predicate devices.

SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
	K203309	K162890
Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations as copings and crowns. It is indicated for cemented or screw mounted single-cemented applications on implants installed on the maxilla or mandible. All digitally designed copings and/or crowns to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	CF Titanium Base for Crown is a titanium abutment placed onto dental implants to provide support for customized prosthetic restorations, as copings or crowns. It is indicated for single-unit restorations, cement-retained or screw-retained in aesthetic areas on implants installed in the maxilla or mandible. All digitally designed copings and/or crowns to be used with the Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	Straumann® SC Variobase® abutments are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented on the Straumann® SC Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. 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.

A comparison of the technological characteristics of the subject device and the predicate and reference devices is provided in the following table.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLES

Table 3. Technological Characteristic Comparison Table – Helix NGM Implants

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	
	K220251 Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K123022** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K162890** Straumann Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments Straumann USA, LLC	**Equivalence Discussion**
Implant-Abutment interface	Grand Morse Internal Connection	Cone Morse Internal Connection		**Similar** All the devices have Internal implant to abutment connection. The difference between the primary predicate and the subject devices has been proven to increase the system resistance (bench testings).
Design	Cylindrical format with double threads; cervical diameter equal to diameter of implant body; Surface: Neoporos and Acqua.	Cylindrical format with double threads; cervical diameter equal to diameter of implant body; Surface: Neoporos and Acqua.	Straight implant with apical taper.	**Identical** Subject devices and Primary Predicate devices present the same design and surface treatment.
Reusable	No	No	No	**Identical** The subject devices and the predicate devices are indicated for single use.
Length (mm)	10; 12; 14	8; 10; 12; 14; 16	10; 12; 14	**Equivalent** Range of lengths for subject devices is contained within the range of lengths for the primary predicate devices and is the same as of the reference predicate devices.
Diameter (Ø) (mm)	2.9	2.9	2.9	**Identical** All the devices present the same diameter.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	
	K220251 Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K123022** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K162890** Straumann Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments Straumann USA, LLC	**Equivalence Discussion**
Material	Commercially Pure Titanium (Grade 4)	Commercially Pure Titanium (Grade 4)	Titanium-13 Zirconium alloy (Roxolid®)	**Identical** Subject devices and Primary Predicate devices are manufactured of the same raw material.
Sterilization Method	Provided sterile via gamma irradiation to an SAL of 10^{-6}.	Provided sterile via gamma irradiation to an SAL of 10^{-6}.		**Identical** Subject devices and primary predicate devices are provided sterile by the same sterilization method.

Table 4. Technological Characteristic Comparison Table – Conventional and Temporary Abutments

	SUBJECT DEVICE	**PRIMARY PREDICATE DEVICE**		
	Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A..	**K123022** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K162890** Straumann Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments Straumann USA, LLC	**Equivalence Discussion**
NGM Exact Click Universal abutments design	Gingival height: 0,8; 1.5, 2.5, and 3.5	Gingival height: 1.5, 2.5, 3.5; 4.5 and 5.5		**Equivalent** Range of lengths for subject devices is very similar to the primary predicate devices and is the same as of the reference predicate devices.
NGM Micro abutments design	Gingival height: 0,8; 1.5, 2.5, and 3.5	Gingival height: 1.5, 2.5, 3.5 and 4.5		**Equivalent** Range of lengths for subject devices is very similar to the primary predicate devices and is the same as of the reference predicate devices.
Healing abutments design	Gingival height: 0,8; 1.5, 2.5, 3.5 and 4.5	Gingival height: 1.5, 2.5, 3.5 and 4.5		**Equivalent** Range of lengths for subject devices is very similar to the primary predicate devices and is the same as of the reference predicate devices.
Temporary abutments design	Gingival height: 0,8; 1.5, 2.5, 3.5 and 4.5		Gingival height: 1.0, 2.0, and 3.0 mm	**Equivalent** Range of lengths for subject devices is very similar to the primary predicate devices and is the same as of the reference predicate devices. The difference between the reference predicate and the subject devices has been mitigated during performance

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE		
	Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A..	**K123022** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K162890** Straumann Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments Straumann USA, LLC	**Equivalence Discussion**
				bench tests.
Attachments Narrow GM design	Gingival height: 0,8; 1.5, 2.5, 3.5 and 4.5 Surface Treatment: NiT Coating	Gingival height: 1.5, 2.5, 3.5 and 4.5 Surface Treatment: NiT Coating		**Equivalent** Range of lengths for subject devices is very similar to the primary predicate devices and is the same as of the reference predicate devices. Both subject and predicate devices present the same surface treatment.
Reusable	No	No	No	**Identical** The subject devices and predicates devices are indicated for single use.
Material	Titanium alloy ASTM F136.	Titanium alloy ASTM F136.	Ti-6Al-7Nb	**Identical** The subject devices and predicates devices are manufactured of the same raw material.
Sterilization Method	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 and the primary predicate devices are provided in sterile condition to an SAL of 1×10^{-6} by the same sterilization method.

Table 5. Technological Characteristic Comparison Table – CAD/CAM Abutments (Titanium Bases)

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K203309** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K162890** Straumann Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments Straumann USA, LLC	
Implant-Abutment interface	Grand Morse Internal Connection	Internal Hex	Small CrossFit® (SC)	**Equivalent** Subject devices and Primary Predicate devices present internal connection implant-abutment interface.
Design	Angulation: 0 Gingival Height: 0.8; 1.5; 2.5; 3.5 and 4.5 Cementable portion height: 4.0 and 6.0	Angulation: 0 Gingival Height: 0.5, 1.0 and 3.0 mm Cementable portion height: 6.0	Angulation: 0 Gingival Height: 1.0, 2.0 and 3.0 mm	**Equivalent** All the devices are straight, the gingival height of the subject devices is similar to the range of gingival height of the predicate devices and bench tests were performed to verify the strength of the system.
Reusable	No	No	No	**Identical** The subject devices and the predicate devices are intended for single use.
Material	Titanium alloy ASTM F136.	Titanium alloy ASTM F136.	Ti-6Al-7Nb	**Identical** The subject devices have the same material of construction as the primary predicate devices.

<table>
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Straumann Ø2.9 mm Bone Level Tapered Implants, SC Closure Cap, SC Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutments
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<tr><td>Top Half Materials</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness (mm)</th><th>Maximum allowable angulation</th></tr>
<tr><td>Coron (CoCr)</td><td>0.3</td><td rowspan="4">30°</td></tr>
<tr><td>IPS e.max CAD</td><td>0.9</td></tr>
<tr><td>Zerion LT</td><td>0.5</td></tr>
<tr><td>Polycon ae*</td><td>1.0</td></tr>
</table>
The Narrow GM Titanium Base with cementable area height of 6 mm allows customization. In case of customization, it is indicated to maintain the minimum height of 4 mm of cementable area.
*Polycon ae is indicated to remain in the mouth only for up to 180 days.</td><td>
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</table>
The CF Titanium Base for Crown with 6 mm cementable height are supplied without angulation, but allow customization by reducing the height of cementable area to 4 mm.
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<tr><td>IPS e.max CAD</td><td>0.9</td></tr>
<tr><td>Zerion LT</td><td>0.4</td></tr>
<tr><td>Polycon ae*</td><td>0.5</td></tr>
</table>
*Polycon ae is indicated to remain in the mouth only for up to 180 days</td><td>Same
The subject top half materials are the same of the cleared top half materials for the primary predicate device and using the same cleared design parameters.</td></tr>
<tr><td>Sterilization Method</td><td>• Provided sterile via Ethylene Oxide to an SAL of $1x10^{-6}$
• If customized on the chairside, must be sterilized before the installation via moist heat (steam), Gravity displacement or dynamic air removal in 132°C (270°F) for 3 minutes exposure.</td><td>• Provided sterile via Ethylene Oxide to an SAL of $1x10^{-6}$
• If customized on the chairside, must be sterilized before the installation via moist heat (steam), Gravity displacement or dynamic air removal in 132°C (270°F) for 3 minutes exposure.</td><td>• Delivered not sterile.
• If customized on the chairside, must be sterilized before the installation via moist heat (steam), Gravity displacement or dynamic air removal in 132°C (270°F) for 4 minutes exposure.</td><td>Identical
The subject devices have the same sterilization methods and same SAL as the primary predicate devices.</td></tr>
</table>

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

Subject and predicate implants have the similar implant-to-abutment interface. Both present the same surfaces and same sterile barrier system. The subject implants are manufactured of the same materials and are sterilized using the same sterilization method as the primary predicate devices. Subject and reference predicate devices present the same range of sizes and similar overall design.

The subject conventional abutments have the same indications for use and same overall design as the primary predicate devices. They also present the same sterilization method and raw materials.

The subject Base abutments have the same indications for use, same maximum angulation and same gingival height as the primary predicate devices. Both, subject devices and primary predicate devices, present the same sterilization method. The subject bases are made of the same material as the primary predicate devices and are indicated to be used with the same restoration materials of the predicate devices. All digitally designed copings and/or crowns for use with the subject Titanium Bases are intended to be sent to Straumann for manufacture at a validated milling center.

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.

Sterilization validation

The subject implants are sterilized by Gamma Irradiation, according to ISO 11137-1 and ISO 11137-2, and the subject abutments by Ethylene Oxide, according to ISO 11135-1 via the over-kill method. The method achieved a Sterility Assurance Level of $1x10^{-6}$.

The Subject devices are not represented to be “pyrogen free”.

CONCLUSION

The subject devices and the predicate 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.