June 23, 2023

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

Re: K223638
Trade/Device Name: Neodent Implant System - Helix Short Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 17, 2023
Received: May 25, 2023

Dear Jennifer Jackson:

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

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

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

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

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

Sincerely,

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)*
K223638

Device Name
Neodent Implant System – Helix Short Implant System

Indications for Use *(Describe)*

Indications for Use for Helix Short Implant:
The Neodent Implant System is recommended for surgical procedures on maxilla or mandible bones. It provides support for prosthetic components such as artificial teeth, thus restoring the 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 Mini Straight, Angled Abutment and screws:
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 Helix Short Attachment:
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 Helix Short Healing Abutment:
This product is used for the maintenance of soft tissue, during the bone integration stage of Neodent implants to be rehabilitated with the late loading technique. The Healing Abutment may be used in the implant installation surgery or the reopening surgery (second surgical stage).

Indications for Use for Helix Short Cover Screw:
This product is used for the maintenance of soft tissue, during the bone integration stage of Neodent implants to be rehabilitated with the late loading technique. The Cover Screw must remain intragingival, preventing the growth of tissue over the implant platform. The seating of the Cover Screw takes place in the conical region of the implant interface.

Indications for Use for Temporary Abutment for Helix Short Implant
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 are indicated to be installed over Helix Short Implants and to provide support for prosthetic structures for up to 6 months.

Indications for Use for Helix Short Titanium Base:
The Helix Short Implant Titanium Base is a titanium base that is placed over Neodent dental implants to provide support for customized prosthetic restorations, such as copings and crowns. It is indicated for single- and multiple-structure restorations, screw- or cement-retained on implants installed in the maxilla or mandible. All digitally-designed copings and/or crowns to be used with the Neodent Titanium Base System must 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.

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510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor	JJGC Indústria e Comércio de Materiais Dentários SA (dba Neodent) Av. Juscelino Kubitschek de Oliveira, 3291 Curitiba, Paraná, 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	22/June/2023
Preparer / Alternate Contact	Bárbara Uzae Regulatory Affairs Analyst E-mail: barbara.uzae@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name Common Name	Neodent Implant System – Helix Short Implant System Endosseous dental implant
Classification Name	Endosseous dental implant
Classification Regulations Product Code	21 CFR 872.3640, Class II / 21 CFR 872.3630, Class II DZE/NHA
Classification Panel Reviewing Branch	Dental Products Panel Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A
Reference Devices	K200586 - Straumann TLX Implant System, Institut Straumann AG K123022 - Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A

K202942 - Straumann® 4 mm Short Implants, Straumann USA, LLC
K203309 – NUVO CF Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A
K220251 - Neodent Implant System - Narrow Implant System, 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 Short Implant:

The Neodent Implant System is recommended for surgical procedures on maxilla or mandible bones. It provides support for prosthetic components such as artificial teeth, thus restoring the 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 Mini Straight, Angled Abutment and screws:

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 Helix Short Attachment:

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 Helix Short Healing Abutment:

This product is used for the maintenance of soft tissue, during the bone integration stage of Neodent implants to be rehabilitated with the late loading technique. The Healing Abutment may be used in the implant installation surgery or the reopening surgery (second surgical stage).

Indications for Use for Helix Short Cover Screw:

This product is used for the maintenance of soft tissue, during the bone integration stage of Neodent implants to be rehabilitated with the late loading technique. The Cover Screw must remain intragingival, preventing the growth of tissue over the implant platform. The seating of the Cover Screw takes place in the conical region of the implant interface.

Indications for Use for Temporary Abutment for Helix Short Implant

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 are indicated to be installed over Helix Short Implants and to provide support for prosthetic structures for up to 6 months.

Indications for Use for Helix Short Titanium Base:

The Helix Short Implant Titanium Base is a titanium base that is placed over Neodent dental implants to provide support for customized prosthetic restorations, such as copings and crowns. It is indicated for single- and multiple-structure restorations, screw- or cement-retained on implants installed in the maxilla or mandible. All digitally-designed copings and/or crowns to be used with the Neodent Titanium Base System must 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), the subject abutments, prosthetic screws and abutment screws are manufactured of Titanium alloy Ti-6Al-4V ELI (ASTM F136) and the restorations placed onto Helix Short Titanium Bases are made of various top half materials.
- The subject implants have a wide cone prosthetic interface with an internal hexagon for short implants lengths available from 4.0 to 7.0; cylindrical shape with double threads and conical apex with three helical flutes for diameters from 3.75 to 7.0mm.
- 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.
- The Helix Short Implant Titanium Base abutments is used as two-piece abutment, where the base is premanufactured from titanium alloy and the top half is created via burn out coping or a digital workflow with CAD/CAM at a validated milling center. The final top half can be created from Ticon, Coron, Zerion LT, IPS e.max, or PMMA. The top half and base pieces are cemented together to form the final abutment.

The various materials that can be used to create top halves for titanium bases and cements were already evaluated and cleared by FDA. Please find below a table with all clearance information for these materials:

Material	Raw material	510(k) of the material
Ticon	Titanium	Exempt according to CFR 872.3710 (subpart E): Dental Base Metal Alloys.
Coron	CoCr alloy	
Zerion LT	Zirconia	K061804
IPS e.max	Lithium Dissilicate	K132209
Polycon ae	PMMA	K071548
Panavia-Kuraray cement	Chemically-active resin	K183537
Ivoclar Multilink cement	Lithium Dissilicate	K130436

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

Table 1 - Technological Characteristic Comparison Table – Helix Short Implants

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	
	Neodent Implant System – Helix Short 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.	**K200586** Straumann TLX Implant System Institut Straumann AG	**K123022** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K202942** Straumann® 4 mm Short Implants Straumann USA, LLC	**Equivalence Discussion**
Indications for Use	The Neodent Implant System is recommended for surgical procedures on maxilla or mandible bones. It provides support for prosthetic components such as artificial teeth, thus restoring the 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 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.	Straumann TLX Implants are suitable for endosteal implantation in the upper and lower jaws and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. TLX Implants can be placed with immediate function on single-tooth and multiunit restorations 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 abutment components.			**Equivalent** Although the language is slightly different, the indications for use of the subject devices is the same as the primary predicate device (K163194) and equivalent to the indications for use of reference predicate device (K200586). The subject and predicate devices are 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.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	
	Neodent Implant System – Helix Short 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.	**K200586** Straumann TLX Implant System Institut Straumann AG	**K123022** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K202942** Straumann® 4 mm Short Implants Straumann USA, LLC	**Equivalence Discussion**
Implant-Abutment interface	Internal Hex	Morse taper	TorcFit (with conical fitting)	Morse taper	Internal octagon	**Equivalent** The subject and predicate devices have internal implant to abutment connection.
Design	Cylindrical body Tissue level	Conical body (Helix) Bone level	Tapered body Tissue level	Cylindrical body Bone level	Cylindrical body Tissue level	**Identical** Cylindrical shape and tissue level as the reference devices.
Reusable	No	No	No	No	No	**Identical** The subject devices and the predicate devices are indicated for single use.
Length (mm)	4.0 / 5.5 / 7.0 / 8.5	8 / 10 / 11.5 / 13 / 16 / 18 (GM Helix)	6.0 / 8.0 / 10 / 12 / 14 / 16 / 18	- 5.0 / 6.0 (WS)	4.0	**Equivalent** Subject implant lengths are within the range of the predicate devices.
Collar length (mm)	1.8	N/A	1.8	N/A	1.8	**Identical** Subject implant and reference devices with tissue level have a collar neck of 1.8mm.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	
	Neodent Implant System – Helix Short 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.	**K200586** Straumann TLX Implant System Institut Straumann AG	**K123022** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K202942** Straumann® 4 mm Short Implants Straumann USA, LLC	**Equivalence Discussion**
Diameter (Ø) (mm)	3.75 / 4.0 / 5.0 / 6.0 / 7.0	3.5 / 3.75 / 4.0 / 4.3 / 5.0 (GM Helix)	3.75 / 4.0 / 4.5 / 5.0 / 5.5 / 6.5	4.0 / 5.0 / 6.0 (WS)	4.1 / 4.8	**Equivalent** Subject device diameters are within the range of diameters of the predicates devices or larger (Ø 7.0). Larger diameters do not represent a worst case in terms of performance.
Material	Commercially pure Titanium grade 4 (ASTM F67)	Commercially pure Titanium grade 4 (ASTM F67)	Titanium-13 Zirconium alloy	Commercially pure titanium grade 4 (ASTM F67)	Titanium-13 Zirconium alloy	**Identical** Identical to the primary predicate device and the Neodent reference devices (K123022)
Sterilization Method	Gamma irradiation to an SAL of $1x10^{-6}$	Gamma irradiation to an SAL of $1x10^{-6}$	Gamma irradiation to an SAL of $1x10^{-6}$	Gamma irradiation to an SAL of $1x10^{-6}$	Gamma irradiation to an SAL of $1x10^{-}$	**Identical** Subject devices and predicate devices are provided sterile by the same sterilization method.
Surface treatment	NeoPoros Acqua	Neoporos Acqua	SLActive®	NeoPoros	SLActive®	**Identical** Identical to the primary predicate device.

Table 2 - Technological Characteristic Comparison Table – Mini Abutments

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	Neodent Implant System – Helix Short Implants 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	**K203309** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**Equivalence** **Discussion**
Indications for Use	**Mini Straight and Angled Abutment:** The Neodent Implant System is recommended for surgical procedures on maxilla or mandible bones. It provides support for prosthetic components such as artificial teeth, thus restoring the chewing function. It may be used in one- or two-stage procedures, multiple restorations, as well as immediate loading when there is good primary stability and adequate occlusal load. Multiple rehabilitations may be splinted rigidly.	**GM Mini Conical and GM Exact Mini Conical 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.	**Multi-Unit Screw Retained Abutment CF (Straight/Angled):** The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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 tooth applications may be rigidly splinted.	**Equivalent** Although the language is slightly different, the indications for use of the subject devices is included into the indications of the predicate devices. The subject and predicate device 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.
Abutment Design	Surface: Machined with pink electrolysis **Mini Straight Abutment:** Gingival height: 0.2, 1.5, 2.5, 3.5, 4.5 **Mini angled abutment:** Gingival height: 0.6, 1.5, 2.5, 3.5 Angulation: 17°	Surface: Machined **GM Mini Conical Abutments:** Gingival height: 0.8; 1.5, 2.5, 3.5, 4.5, 5.5 **GM Exact Mini Conical Abutments:** Gingival height: 1.5, 2.5, 3.5 Angulation: 17° and 30°	Surface: Machined and electrolysis **Straight Abutment:** Gingival height: 1.0, 2.0, 3.0, 4.0 and 5.0 mm; **Angled Abutment:** Gingival height: 2.0 and 3.0 mm Angulation: 17° and 30°	**Equivalent** The subject device have the same surface of reference predicate device and similar geometry and range of dimensions and angulation of primary predicate device.
Single Use	Yes	Yes	Yes	**Identical** The subject devices and predicates devices are indicated for single use.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	Neodent Implant System – Helix Short Implants 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	**K203309** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**Equivalence** **Discussion**
Raw material	Titanium alloy ASTM F136.	Titanium alloy ASTM F136.	Titanium alloy ASTM F136.	**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 3 - Technological Characteristic Comparison Table – Attachments

	SUBJECT DEVICE	REFERENCE DEVICE	
	Neodent Implant System – Helix Short Implants System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K220251** Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A	**Equivalence** **Discussion**
Indications for Use	**Helix Short Attachment:** The Neodent Implant System is recommended for surgical procedures on maxilla or mandible bones. It provides support for prosthetic components such as artificial teeth, thus restoring the chewing function. It may be used in one- or two-stage procedures, multiple unit restorations, as well as immediate loading when there is primary stability and adequate occlusal load.	**NGM Attachments** 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** Although the language is slightly different, the indications for use of the subject devices is the same of the indications of the predicate devices. The subject and predicate device are 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.

	SUBJECT DEVICE	REFERENCE DEVICE	
	Neodent Implant System – Helix Short Implants System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K220251** Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A	**Equivalence Discussion**
Abutment Design	**HS Attachments:** Gingival height: 0.2, 1.5, 2.5, 3.5 Surface Treatment: TiN Coating	**NGM Attachments:** Gingival height: 0.8; 1.5, 2.5, 3.5 and 4.5 Surface Treatment: TiN Coating	**Equivalent** The subject devices and predicates devices have the same surface treatment and similar geometry and range of dimensions.
Single Use	Yes	Yes	**Identical** The subject devices and predicates devices are indicated for single use.
Raw material	Titanium alloy ASTM F136.	Titanium alloy ASTM F136.	**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}	**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 4 - Technological Characteristic Comparison Table – Healing Abutment and Cover Screw

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	Neodent Implant System – Helix Short Implants 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	**K203309** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**Equivalence** **Discussion**
Indications for Use	**Helix Short Healing Abutment and Cover Screw:** This product is used for the maintenance of soft tissue, during the bone integration stage of Neodent implants to be rehabilitated with the late loading technique. The Healing Abutment may be used in the implant installation surgery or the reopening surgery (second surgical stage). The Cover Screw must remain intragingival, preventing the growth of tissue over the implant platform. The seating of the Cover Screw takes place in the conical region of the implant interface.	**GM Healing abutment and Cover Screw:** 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.	**NUVO CF Healing Abutments and Cover Screws:** The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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 tooth applications may be rigidly splinted.	**Equivalent** Although the language is different, the indications for use of the subject devices are the same of predicate devices. The subject and the predicate devices are used to the maintenance of soft tissue, during the bone integration stage of implants to be rehabilitated with the late loading technique. The indications for use are written differently because those for the predicate devices are talking about the implant system as a whole and not the healing abutment and cover screws specifically.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	Neodent Implant System – Helix Short Implants 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	**K203309** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**Equivalence** **Discussion**
Abutment Design	Surface: Machined with pink electrolysis. **HS Healing Abutment:** Gingival height: 1.5, 2.5, 3.5, 4.5, 5.5 **Cover Screw:** 0.35 mm height above the implant platform level	Surface: Machined **GM Healing abutment:** Gingival height: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 **Cover Screw:** Gingival height: at the bone level, or with a height of 2 mm	Surface: Machined with pink electrolysis. **NUVO CF Healing Abutments and Cover Screws:** Gingival height: 1.0, 2.0, 3.0, 4.0 and 5.0 **Cover Screw:** 0.3, 2. 0 mm	**Equivalent** The subject devices and the reference predicate devices have the same surface treatment. The subject and predicate devices have similar geometry and dimensions.
Single Use	Yes	Yes	Yes	**Identical** The subject devices and predicates devices are indicated for single use.
Raw material	Titanium alloy ASTM F136.	Titanium alloy ASTM F136.	Titanium alloy ASTM F136.	**Identical** The subject devices and predicate 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 predicate devices are provided in sterile condition to an SAL of 1 x 10^{-6} by the same sterilization method.

Table 5 - Technological Characteristic Comparison Table – Temporary Abutments

	SUBJECT DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	
	Neodent Implant System – Helix Short Implants System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K203309** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K220251** Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A	**Equivalence Discussion**
Indications for Use	**Temporary Abutment:** The Implant System is indicated for surgical procedures on maxilla or mandible bones, providing support for dental prostheses with the purpose of restoring the chewing function as well as aesthetics. It may be used in one- or two-stage procedures, single or multiple restorations, and immediate loading when there is good primary stability and adequate occlusal load. Temporary Abutments are indicated to be installed over Helix Short Implants and to provide support for prosthetic structures for up to 6 months.	**Temporary Abutments:** The Implant System is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order 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 tooth applications may be rigidly splinted.	**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.	**Equivalent** Although the language is slightly different, the indications for use of the subject devices is included into the indications of the predicate devices. The subject and predicate devices are intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices such as artificial teeth in order to restore chewing function. It may be used in one- or two-stage procedures, single or multiple restorations, and immediate loading when there is good primary stability and adequate occlusal load. All are indicated to be used for up to 6 months.
Abutment Design	**Temporary Abutments:** Gingival height: 0.2; 1.5; 2.5; 3.5 Surface: Machined with pink electrolysis.	**Temporary Abutments:** Gingival height: 0.5, 1.0 and 3.0 mm Surface: Machined with pink electrolysis.	**Temporary Abutments:** Gingival height: 0,8; 1.5, 2.5, 3.5 and 4.5 Surface: Machined	**Equivalent** The subject devices and the primary predicate devices have the same surface treatment. The subject and predicate devices have similar geometry and dimensions.

	SUBJECT DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	
	Neodent Implant System – Helix Short Implants System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K203309** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K220251** Neodent Implant System - Narrow Implant System JJGC Indústria e Comércio de Materiais Dentários S.A	**Equivalence Discussion**
Single Use	Yes	Yes	Yes	**Identical** The subject devices and predicates devices are indicated for single use.
Raw material	Titanium alloy ASTM F136.	Titanium alloy ASTM F136.	Titanium alloy ASTM F136.	**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 6 - Technological Characteristic Comparison Table – Helix Short Titanium Bases

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
	Subject Neodent Implant System – Titanium Bases for Helix Short Implant Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K203309** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Indications for Use	The Helix Short Implant Titanium Base is a titanium base that is placed over Neodent dental implants to provide support for customized prosthetic restorations, such as copings and crowns. It is indicated for single- and multiple-structure restorations, screw- or cement-retained on implants installed in the maxilla or mandible. All digitally-designed copings and/or crowns to be used with the Neodent Titanium Base System must 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.	Titanium Base for Bridge: CF Titanium Base for Bridge is a titanium abutment placed onto dental implants to provide support for customized prosthetic restorations. The CF Titanium Base for Bridge is indicated for cement or screw-retained multi-unit restorations. 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. Titanium Base for Crown: 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.	**Equivalent** Although the language is slightly different, the indications for use of the subject and predicate devices are the same. The subject and predicate devices are intended to place onto dental implants to provide support for customized prosthetic restorations, such as copings and crowns.

<table>
<tr><th>COMPARISON</th><th>SUBJECT DEVICES
Subject
Neodent Implant System – Titanium Bases for Helix Short Implant Line
JJGC Indústria e Comércio de Materiais Dentários S.A.</th><th>PRIMARY PREDICATE
K163194
Neodent Implant System – GM Line
JJGC Indústria e Comércio de Materiais Dentários S.A.</th><th>REFERENCE DEVICE
K203309
NUVO CF Implant System
JJGC Indústria e Comércio de Materiais Dentários S.A.</th><th>EQUIVALENCE DISCUSSION</th></tr>
<tr><td>Abutment Design</td><td>Cylindrical format provided in different gingival heights.
Angulation: 0°
Gingival Heights: 0.2; 1.5, 2.5 and 3.5 mm
Surface: Machined and Electrolysis
Cementable portion height: 6.0 and 4.5 mm</td><td>Cylindrical format provided in different gingival heights.
Angulation: 0°
Gingival Heights: 0.8; 1.5; 2.5; 3.5; 4.5 mm
Surface: Machined
Cementable portion height: 6.0 and 4.0</td><td>Conical format provided in different gingival heights.
Angulation: 0°
Gingival Heights: 0.5; 1.0; 3 mm
Surface: Machined and Electrolysis
Cementable portion height: 6.0 and 4.5 mm</td><td>Equivalent
The subject devices and the reference predicate devices share the same surface finish, similar geometry and range of dimensions.</td></tr>
<tr><td>Single Use</td><td>Yes</td><td>Yes</td><td>Yes</td><td>Identical
Subject and predicate devices are not reusable.</td></tr>
<tr><td>Raw material</td><td>Titanium Alloy (Ti-6Al-4V) – according to ASTM F136.</td><td>Titanium Alloy (Ti-6Al-4V) – according to ASTM F136.</td><td>Titanium Alloy (Ti-6Al-4V) – according to ASTM F136.</td><td>Identical
The subject and predicate devices are manufactured of the same raw material.</td></tr>
<tr><td>Top Half Materials</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness</th><th>Maximum allowable angulation</th></tr>
<tr><td>Coron (CoCr)</td><td>0.3</td><td rowspan="5">16°</td></tr>
<tr><td>Ticon (Titanium)</td><td>0.4</td></tr>
<tr><td>IPS e.max</td><td>0.9</td></tr>
<tr><td>Zerion LT</td><td>0.5</td></tr>
<tr><td>Polycon ae*(PMMA)</td><td>1.0</td></tr>
</table>
* Polycon ae material is only recommended for temporary/provisional prosthetic restorations.
</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness</th><th>Maximum allowable angulation</th></tr>
<tr><td>Coron (CoCr)</td><td>0.3</td><td rowspan="6">30°</td></tr>
<tr><td>Ticon (Titanium)</td><td>0.4</td></tr>
<tr><td>Zerion LT</td><td>0.5</td></tr>
<tr><td>IPS e.max CAD</td><td>0.9</td></tr>
<tr><td>3M ESPE Lava Plus Zirconia</td><td>0.7</td></tr>
<tr><td>Polycon ae*(PMMA)</td><td>1.0</td></tr>
</table>
* Polycon ae material is only recommended for temporary/provisional prosthetic restorations.
</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness</th><th>Maximum allowable angulation</th></tr>
<tr><td>Coron (CoCr)</td><td>0.3</td><td rowspan="4">30°</td></tr>
<tr><td>Zerion LT</td><td>0.5</td></tr>
<tr><td>IPS e.max CAD</td><td>0.9</td></tr>
<tr><td>Polycon ae*(PMMA)</td><td>1.0</td></tr>
</table>
*Polycon ae is indicated to remain in the mouth only for up to 180 days.
</td><td>Equivalent
The top half materials of the subject devices are contained within the scope of the top half materials of the predicate device. The maximum allowable angulation of subject device is smaller than the maximum angulation of the predicate devices, therefore it is less critical.</td></tr>
</table>

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
	Subject Neodent Implant System – Titanium Bases for Helix Short Implant Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K203309** NUVO CF Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	
Sterilization Method	• Provided sterile via Ethylene Oxide to an SAL of 1x10-6 The final prosthesis must be sterilized by the end used before installation in the mouth via moist heat (steam), gravity displacement or dynamic air removal in 132°C (270°F) for 3 minute exposure.	• Provided sterile via Ethylene Oxide to an SAL of $1x10^{-6}$ To be sterilized by user after superstructure cementation, before placed in patient mouth (moist steam sterilization).	• 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 minute exposure.	**Identical** The subject devices and predicate devices share the same sterilization method.

The subject implants have equivalent indications for use and 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, are manufactured of the same materials and are sterilized using the same sterilization method. Subject and reference predicate devices present the same range of sizes and similar overall design.

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

The subject Base abutments have the equivalent indications for use and same sterilization method as the primary predicate devices. Both, subject and primary predicate devices, are made of the same material. The top half materials of the subject devices are contained within the scope of the top half materials of the predicate devices and 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 as the predicate devices. The subject devices and the reference predicate devices share the same surface finish, similar geometry and range of dimensions.

Overall, the subject devices are substantially equivalent to the predicate devices as follows:
- same intended use,
- same operating principle,
- incorporate the equivalent basic design,
- incorporate the same materials, and
- are sterilized using the same materials and processes

PERFORMANCE DATA

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.

Torsion Test was performed to evaluate Helix Short Implant under static torsional loading. The results met the acceptance criteria. Insertion test was performed to evaluate the insertion torque of the Helix Short System when it is inserted in bones type I, II, IIII and IV.

The Implant Surface Area simulation and Pull Out Test were also made to evaluate and represent the clinical use of the subject implants. Results demonstrated that the subject devices, despite having a slightly smaller surface area than the reference devices, presented a higher BIC rate and pull out resistance upon placement. Thus, the subject devices exhibit a level of benchtop performance equivalent to that reviewed for the reference device.

MR Compatibility testing

The MR compatibility was performed to access the risk of exposing patients who have implantable medical devices. An assessment was made to demonstrate that the subject devices do not configure a new worst case and can be represented by the previously conducted studies reviewed for reference devices, since both have the same raw material and similar dimensions. The subject devices are therefore MR conditional devices and a patient treated with the subject devices can be safely scanned observing the parameters previously established per reference devices.

Surface treatment

The surface treatments applied to subject devices are identical to these applied and previously evaluated for primary predicate devices. Although some reference devices have a surface with different nomenclature, the chemical processes applied to the surface are similar to create the roughness surface. Acqua implants are submitted to an additional step in order to increase their hydrophilicity, as already cleared for primary predicate device.

Sterilization validation

Sterilization of the subject implants via gamma irradiation according to ISO 11137-1 Sterilization of health care products -Radiation -Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices and ISO 11137-2 Sterilization of health care products -Radiation -Part 2: Establishing the sterilization dose. A minimum Sterility Assurance Level (SAL) of 1 x 10^{-6} has been validated.

Sterilization of the subject abutments via ethylene oxide gas using the overkill method has been performed according to the requirements of ISO 11135-1 Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements For Development, Validation and Routine Control of a Sterilization Process For Medical Devices. A minimum Sterility Assurance Level (SAL) of 1 x 10^{-6} has been validated.

Endotoxin testing (LAL)

The LAL Endotoxin Analysis is the method used to determine that the device meets pyrogen limit specifications, based in the referred FDA guidance (510(k) Submission for Devices Labeled as Sterile, issued on 21 January 2016). Routine endotoxin testing is performed with representative devices as an assessment of environmentally derived pyrogenicity. Subject devices meet the acceptance criteria for endotoxin levels as well as the primary predicate and reference devices. The subject devices are not represented to be “pyrogen free”.

Shelf Life validation

The expiration date of the products was determined considering the integrity of the product and the packaging tests after shelf life testing. The packaging of the subject Helix Short Implant System is identical to the packaging of the primary predicate and reference devices. The shelf life for devices provided sterile is 5 years, except Helix Short Acqua Implants that have a shelf life of 4 years.

Biocompatibility

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

Cytotoxicity testing was performed per ISO 10993-5. Chemical characterization was performed per ISO 10993-18.

Biocompatibility sample preparation was performed per ISO 10993-12. Biological Safety Assessment guided by ISO 10993-1.

EO Residuals evaluation was performed in accordance with 10993-7.

No new issues of biocompatibility are raised for the subject devices when compared to primary predicate and reference devices. Therefore, no additional biocompatibility testing was required.

CONCLUSION

The data included in this submission demonstrate that the subject system is substantially equivalent to the primary predicate and reference devices in terms of intended use, design, technological characteristics, mechanical properties, shelf life, sterilization method and material.