December 4, 2024

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

Re: K242686
Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 6, 2024
Received: September 6, 2024

Dear Jennifer Jackson:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

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

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242686

Device Name
Neodent Implant System

Indications for Use *(Describe)*

NeoConvert Solution:
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. The NeoConvert Solution may be used with single-stage or two-stage procedures, for temporary multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Direct Screw to MUA:
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. The Direct Screw to MUA may be used with single-stage or two-stage procedures, for screw-retained multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. All digitally designed personalized copings to be used with the Direct to Multi Unit Abutment Screw are intended to be sent to Straumann for manufacture at a validated milling center.

GM Attachment TiN 30°:
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. The GM Attachment TiN 30° may be used with single-stage or two-stage procedures, for multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

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

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810, USA Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: JJGC Indústria e Comércio de Materiais Dentários S.A (dba Neodent) Av. Juscelino Kubitschek de Oliveira, 3291 Curitiba, Paraná, Brazil 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person:	Jennifer M. Jackson, MS, RAC Sr. Director, Regulatory Affairs and Quality Phone Number: +1 978 747-2509 Fax Number: +1 978 747-0023 Email: jennifer.jackson@straumann.com
Prepared By & Alternate Contact:	Leticia Milani Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA
Date Prepared:	December 2, 2024

Name of the Device

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

Predicate Device(s)

NeoConvert Solution:

Primary Predicate:

K163194 *Neodent Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*

Reference Devices:

K101945 *Neodent Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*

K193234 *Nuvo IF Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*

Direct Screw to MUA:

Primary Predicate:

K163194 *Neodent Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*

Reference Devices:

K162890 *Straumann SC Variobase Abutments (Straumann USA, LLC)*

K180536 *Neodent Implant System - GM Line (JJGC Indústria e Comércio de Materiais Dentários S.A)*

K192229 *GM Titanium Base for Bridge (JJGC Indústria e Comércio de Materiais Dentários S.A)*

K202452 *NobelProcera Zirconia Implant Bridge (Nobel Biocare AB)*

K203309 *NUVO CF Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*

K203542 *Mini Abutment 60°(*JJGC Indústria e Comércio de Materiais Dentários S.A)

K220251 *GM Narrow Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*

K223638 *Helix Short Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*

GM Attachment TiN 30°:

Primary Predicate:

K163194 *Neodent Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*

Reference Devices:

K173902 *Neodent Implant System – GM Line (JJGC Indústria e Comércio de Materiais Dentários S.A)*

K192229 *GM Titanium Base for Bridge (JJGC Indústria e Comércio de Materiais Dentários S.A)*

MRI:

K182620 *MRI Compatibility for Existing Neodent Implant System*

K242686 – Traditional 510(k) Submission

Neodent Implant System

510(k) Summary

Device Description

This premarket notification includes the following additions to the Neodent Implant System:

- NeoConvert Solution
- Direct Screw to MUA
- GM Attachment TiN 30°

The Neodent Multi-Unit Abutments proposed on this submission are similar to devices already cleared in previous submissions of Neodent Implant System, according to predicate devices described above. This submission intends to expand the portfolio of Neodent Abutments with these new solutions for multi-unit restorations, to provide more treatment options to customers.

The NeoConvert Solution is a technique comprised by some abutments and instruments (not subject of this submission) used for converting removable temporary prosthesis into a screw-retained fixed temporary prosthesis.

The Direct Screw to MUA is a prosthetic component designed to fix planned and digitally designed multi-unit milled restorations directly onto mini or micro abutments, eliminating the need for using the passive seating cylinder to restore chewing function.

The GM Attachment TiN 30° is a prosthetic component used to stabilize implant-mucosa-supported removable full prosthesis (retained on the implant and supported on the mucosa), on implants installed in the maxilla or mandible.

Although all these three new solutions are compatible with the same implants and components of Neodent Implant System and used for multiple unit rehabilitation, they are not used in conjunction with each other.

Intended Use

NeoConvert Solution:

Instruments and components used to perform the procedure of converting removable prostheses into temporary fixed prostheses on GM line implants installed in the maxilla and/or mandible.

Direct Screw to MUA:

The Direct Screw to MUA is suitable for attaching the multiple restoration milled from a CAD/CAM library to the prosthetic abutment (mini or micro abutments).

GM Attachment TiN 30°:

This product is used to stabilize implant-mucosa supported removable full prostheses (retained on the implant and supported on the mucosa), on implants installed in the maxilla or mandibula. It can be used in immediate or conventional rehabilitation procedures.

Indications for Use

NeoConvert Solution:

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. The NeoConvert Solution may be used with single-stage or two-stage procedures, for temporary multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Direct Screw to MUA:

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. The Direct Screw to MUA may be used with single-stage or two-stage procedures, for screw-retained multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. All digitally designed personalized copings to be used with the Direct to Multi Unit Abutment Screw are intended to be sent to Straumann for manufacture at a validated milling center.

GM Attachment TiN 30°:

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. The GM Attachment TiN 30° may be used with single-stage or two-stage procedures, for multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in the following tables:

Table 1 – Table of Substantial Equivalence NeoConvert

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
K Number	***K242686*** ***Neodent Implant System***	***K163194*** ***Neodent Implant System***	***K101945*** ***Neodent Implant System***	***K193234*** ***Nuvo IF Implant System***
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. The NeoConvert Solution may be used with single-stage or two-stage procedures, for temporary 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.	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 tooth applications may be rigidly splinted.	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.
Material	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.
Overall dimensions	NeoConvert Screw: • Laying diameter: 1.4 mm • Height: 3.7 mm NeoConvert Coping: • Laying diameter: 4.8 mm • Height: 5.0 and 6.0 mm NeoConvert Distal Bar: • Laying diameter: 4.8 mm • Height: 5 mm	Mini Conical Abutment Coping Screw: • Laying diameter: 1.4 mm • Height: 3.7 mm	Mini Conical Abutment Coping: • Laying diameter: 4.8 mm • Height: 12 mm	Nuvo Distal Bar: • Laying diameter: 5.2 mm • Height: 10 mm
Commercially Supplied	NeoConvert Coping and Screw: One cavity blister with five units. NeoConvert Distal Bar: Two cavity blister with one unit and one screw.	Mini Conical Abutment Coping Screw: One cavity blister with one unit.	Mini Conical Abutment Coping: Two cavity blister with one unit and one screw.	Nuvo Distal Bar: Two cavities blister with one unit and one screw.
Single use	Yes	Yes	Yes	Yes

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
K Number	***K242686*** ***Neodent Implant System***	***K163194*** ***Neodent Implant System***	***K101945*** ***Neodent Implant System***	***K193234*** ***Nuvo IF Implant System***
Sterilization Method	Provided sterile via Ethylene Oxide. The coping and screw, if opened and not used, must be terminally sterilized by user via moist heat with cycle parameters validated to a SAL of $1x10^{-6}$.	Provided sterile via Ethylene Oxide.	Provided sterile via Ethylene Oxide. Terminally sterilized by user via moist heat with cycle parameters validated to a SAL of $1x10^{-6}$.	Provided sterile via Ethylene Oxide.

Table 2 – Table of Substantial Equivalence Direct Screw to MUA (Zygomatic Implants)

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
K Number	***K242686*** ***Neodent Implant System***	***K163194*** ***Neodent Implant System***	***K202452*** ***NobelProcera Zirconia Implant Bridge***	***K203542*** ***Mini Abutment 60°***
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. The Direct Screw to MUA may be used with single-stage or two-stage procedures, for screw-retained multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. All digitally designed personalized copings to be used with the Direct to Multi Unit Abutment Screw are intended to be sent to Straumann for manufacture at a validated milling center.	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 NobelProcera Zirconia Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.	The Mini Conical Abutments are indicated for use with Zygomatic Implants, in case of severe jaw resorption, in order to restore patient aesthetics and chewing function. It may be used with single-stage or two-stage procedures, for multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
Material	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.
Overall dimensions	Diameter of the screw head: 2.2 mm Height of screw head: 1.7 mm Total height: 4.1 mm	Diameter of the screw head: 1.9 mm Diameter of the external thread: 1.4 mm Height of screw head: 1.7 mm Total height: 3.7 mm	Diameter of the screw head: 2.0 mm Total height: 4.0 mm	
Commercially Supplied	One cavity blister with five units.	One cavity blister with one units.		
Single Use	Yes	Yes	Yes	Yes
Sterilization Method	Provided non-sterile. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, with an exposure time of 3 minutes at 132°C (270°F).		Provided non-sterile. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, at 132°C (270°F) or 134°C (273°F).	
Top Half Material	**Material** / **Minimum thickness** N!ce® HT – 0.4 mm N!ce® LT – 0.4 mm N!ce® XT – 0.4 mm Ticon® – 0.4 mm Coron® – 0.4 mm			

Table 3 – Table of Substantial Equivalence Direct Screw to MUA (GM Implants)

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	
K Number	***K242686*** ***Neodent Implant System***	***K163194*** ***Neodent Implant System***	***K192229*** ***GM Titanium Base for Bridge***	***K203309*** ***NUVO CF Implant System***
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. The Direct Screw to MUA may be used with single-stage or two-stage procedures, for screw-retained multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. All digitally designed personalized copings to be used with the Direct to Multi Unit Abutment Screw are intended to be sent to Straumann for manufacture at a validated milling center.	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.	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-retained single or multi-unit restorations or screw-retained single restorations. 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.	The CF Titanium Base for Bridge is a titanium abutment placed onto dental implants to provide support for customized prosthetic restorations (multiple structures). It is indicated for multi-unit restorations, cement-retained or screw-retained in aesthetic areas on implants installed in the maxilla or mandible.
Material	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.
Overall dimensions	Diameter of the screw head: 2.2 mm Height of screw head: 1.7 mm Total height: 4.1 mm	Diameter of the screw head: 1.9 mm Diameter of the external thread: 1.4 mm Height of screw head: 1.7 mm Total height: 3.7 mm	Diameter: 3.5mm Cementable area height 4.0mm Gingival Height: 0.8 mm	Diameter: 3.5 mm Cementable area height: 4.5 mm Gingival height: 0.5 mm
Commercially Supplied	One cavity blister with five units.	One cavity blister with one units.	Two cavity blister with one unit and one screw.	Two cavity blister with one unit and one screw.
Single Use	Yes	Yes	Yes	Yes
Sterilization Method	Provided non-sterile. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, with an exposure time of 3 minutes at 132°C (270°F).		Provided sterile by Ethylene Oxide. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, at 132°C (270°F).	Provided sterile by Ethylene Oxide. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, at 132°C (270°F).
Top Half Material	**Material** / **Minimum thickness** N!ce® HT – 0.4 mm N!ce® LT – 0.4 mm N!ce® XT – 0.4 mm Ticon® – 0.4 mm Coron® – 0.4 mm Polycon® ae – 1.0 mm *Polycon ae is indicated to remain in the mouth only for up to 180 days		**Material** / **Minimum thickness** N!ce® – 1.0 mm Zerion LT – 0.5 mm Ticon® – 0.4 mm Coron® – 0.3 mm Polycon® ae – 1.0 mm *Polycon ae is indicated to remain in the mouth only for up to 180 days	**Material** / **Minimum thickness** Zerion LT – 0.5 mm Ticon® – 0.4 mm Coron® – 0.3 mm Polycon® ae – 1.0 mm *Polycon ae is indicated to remain in the mouth only for up to 180 days

Table 4 – Table of Substantial Equivalence Direct Screw to MUA (HS Implants)

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
K Number	***K242686*** ***Neodent Implant System***	***K163194*** ***Neodent Implant System***	***K223638*** ***Helix Short Implant System***
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. The Direct Screw to MUA may be used with single-stage or two-stage procedures, for screw-retained multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. All digitally designed personalized copings to be used with the Direct to Multi Unit Abutment Screw are intended to be sent to Straumann for manufacture at a validated milling center.	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 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.
Material	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.
Overall dimensions	Diameter of the screw head: 2.2 mm Height of screw head: 1.7 mm Total height: 4.1 mm	Diameter of the screw head: 1.9 mm Diameter of the external thread: 1.4 mm Height of screw head: 1.7 mm Total height: 3.7 mm	Diameter: 4.8 mm Cementable area height 4.5 mm Gingival Height: 0.2 mm
Commerciall y Supplied	One cavity blister with five units.	One cavity blister with one units.	
Single Use	Yes	Yes	Yes
Sterilization Method	Provided non-sterile. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, with an exposure time of 3 minutes at 132°C (270°F).		Provided sterile by Ethylene Oxide. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, at 132°C (270°F).
Top Half Material	**Material** / **Minimum thickness** N!ce® HT / 0.4 mm N!ce® LT / 0.4 mm N!ce® XT / 0.4 mm Ticon® / 0.4 mm Coron® / 0.4 mm Polycon® ae / 1.0 mm *Polycon ae is indicated to remain in the mouth only for up to 180 days		**Material** / **Minimum thickness** IPS e.max CAD / 0.9 mm Ticon® / 0.4 mm Coron® / 0.3 mm Polycon® ae / 1.0 mm *Polycon ae is indicated to remain in the mouth only for up to 180 days

Table 5 – Table of Substantial Equivalence Direct Screw to MUA (NGM Implants)

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	
K Number	***K242686*** ***Neodent Multi-Unit Abutments***	***K163194*** ***Neodent Implant System***	***K162890*** ***Straumann SC Variobase Abutments***	***K220251*** ***Narrow Implant System***
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 procedures, for screw-retained multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. All digitally designed personalized copings to be used with the Direct to Multi Unit Abutment Screw are intended to be sent to Straumann for manufacture at a validated milling center.	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® Variobase® abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of edentulous or partially edentulous patients with crowns, bridges, or full-arch 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 one 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.
Material	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.	Titanium-vanadium alloy.	Titanium alloy, according to ASTM F136.
Overall dimensions	Diameter of the screw head: 2.2 mm Height of screw head: 1.7 mm Total height: 4.1 mm	Diameter of the screw head: 1.9 mm Diameter of the external thread: 1.4 mm Height of screw head: 1.7 mm Total height: 3.7 mm	Diameter: 3.3 – 4.3 mm Gingival Height: 3.0 mm Total height: 6.7 – 8.7 mm	Diameter: 3.5 mm Gingival height: 3.5 mm
Commercially Supplied	One cavity blister with five units.	One cavity blister with one units.		One cavity blister with one unit.
Single Use	Yes	Yes	Yes	Yes
Sterilization Method	Provided non-sterile. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, with an exposure time of 3 minutes at 132°C (270°F).			Provided sterile by Ethylene Oxide. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, at 132°C (270°F).
Top Half Material	**Material** / **Minimum thickness** N!ce® HT – 0.4 mm N!ce® LT – 0.4 mm N!ce® XT – 0.4 mm Ticon® – 0.4 mm Coron® – 0.4 mm Polycon® ae – 1.0 mm *Polycon ae is indicated to remain in the mouth only for up to 180 days		**Material** / **Minimum thickness** N!ce® HT – 0.4 mm N!ce® LT – 0.4 mm N!ce® XT – 0.5 mm Polycon® ae – 0.5 mm *Polycon ae is indicated to remain in the mouth only for up to 180 days	**Material** / **Minimum thickness** Ticon® – 0.4 mm Coron® – 0.4 mm *Polycon ae is indicated to remain in the mouth only for up to 180 days

Table 6 – Table of Substantial Equivalence GM Attachment TiN 30º

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE		REFERENCE PREDICATE DEVICE
K Number	***K242686*** ***Neodent Implant System***	***K163194*** ***Neodent Implant System***	***K173902*** ***Neodent Implant System –GM Line***	***K192229*** ***GM Titanium Base for Bridge***
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. The GM Attachment TiN 30° may be used with single-stage or two-stage procedures, for 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.	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.	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-retained single or multi-unit restorations or screw-retained single restorations. 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.
Material	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.
Overall dimensions	Gingival height: 1.5, 2.5, 3.5, 4.5 and 5.5 mm Angulation: 30°	Gingival height: 0.8, 1.5, 2.5, 3.5, 4.5 and 5.5 mm Angulation: 0°	Gingival height: 0.8, 1.5, 2.5, 3.5, 4.5 and 5.5 mm Angulation: 15°	Cementable area height: 4.0 mm Gingival height: 0.8 mm Maximum angulation: 30°
Commercially Supplied	One cavity blister with one unit.	One cavity blister with one unit.	One cavity blister with one unit.	
Single Use	Yes	Yes	Yes	
Sterilization Method	Provided sterile by ethylene oxide.	Provided sterile by Ethylene Oxide. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, at 132°C (270°F).	Provided sterile by ethylene oxide.	

Performance Testing

Bench Testing

Assessments regarding dynamic fatigue testing were conducted according to the FDA guidance document “Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments” and ISO 14801 “Dentistry — Implants — Dynamic loading test for endosseous dental implants”. For dynamic fatigue tests, the results demonstrated that in identical conditions, the subject devices exhibit a level of performance equal or better than the predicate and reference devices. Torsion tests were also performed to evaluate the strength of the screw used to fix all subject abutments against maximum twisting forces. The results prove that there is an adequate torsion strength in accordance with the installation torque recommended in IFU.

SEM images made after fatigue loading test were included to demonstrate that the personalized copings made from Zirconia and PMMA present acceptable levels of wear in the areas of the screw seating.

MRI Compatibility Testing

An assessment was made to demonstrate that the MR conditional labeling from K182620 is applicable to the subject devices, and a patient treated with them can be safely scanned observing the parameters previously established per reference devices.

Biocompatibility Testing

Assessments regarding biological compatibility were performed according to ISO 10993-1 “*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*” and to the FDA Guidance document “*Use of International Standard ISO 10993- 1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process’, Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016*”.

Representative samples of the subject devices were subjected to the following:

• Biological Safety Assessment guided by ISO 10993-1.

• Chemical characterization was performed per ISO 10993-18.

• Cytotoxicity testing was performed per ISO 10993-5.

The subject devices are equivalent in material and manufacturing processes to the primary predicate and reference devices, therefore, no new issues regarding biocompatibility were raised and no additional biocompatibility testing was required.

Sterilization validation

For the proposed devices supplied sterile via Ethylene Oxide (EO), the method was validated to a sterility assurance level (SAL) of $1x10^{-6}$ in accordance with ISO 11135:2014, "*Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*". EO sterilization residuals have been verified to be less than the maximum allowable limits as defined in ISO 10993-7 "*Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals*".

For proposed devices that must be sterilized before installation in the mouth, the steam sterilization methos was validated according to ISO 17665 – 1 "*Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*", using the parameters described in IFU.

The sterilization of the subject device are identical to the sterilization already cleared for the primary and reference predicate devices.

Shelf Life

The expiration date of the devices was determined considering the integrity of the product and the packaging tests after shelf-life testing. The packaging of the Neodent Multi-Unit Abutments is identical to the packaging of the primary predicate and reference devices. The Shelf Life for Neodent Multi-Unit Abutments is 5 years.

Conclusion

The subject devices and the primary predicate device have similar indications for use, intended use, design, raw material and overall dimensions. Thus, all documentation submitted in this premarket notification demonstrate that the proposed devices are substantially equivalent to the primary predicate and reference devices.