



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service  
Food and Drug Administration  
10903 New Hampshire Avenue  
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JJGC Industria e Comercio de Materiais Dentarios SA  
c/o Jennifer Jackson  
Director, Regulatory Affairs & Quality Management  
Straumann USA, LLC  
60 Minuteman Road  
Andover, Massachusetts 01810

July 14, 2017

Re: K163194

Trade/Device Name: Neodent Implant System - GM Line  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: Class II  
Product Code: DZE, NHA  
Dated: June 13, 2017  
Received: June 15, 2017

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. 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

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Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Mary S. Runner -A**

Lori A. Wiggins, MPT, CLT  
Acting Director

Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K163194

Device Name

Neodent Implant System - GM Line

Indications for Use (Describe)

Indications for Use for GM implants and 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 GM Titanium Base abutments:

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 for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for GM Pro Peek Abutments:

The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.

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	<p>Straumann USA, LLC          60 Minuteman Road          Andover, MA 01810          Registration No.: 1222315          Owner/Operator No.: 9005052</p> <p>on behalf of:          JJGC Indústria e Comércio de Materiais Dentários SA          Av. Juscelino Kubitschek de Olivera, 3291          Curitiba, Parana, BRAZIL 81270-200          Registration No.: 3008261720          Owner/Operator No.: 10031702</p>
Contact Person	<p>Jennifer M. Jackson, MS          Director, Regulatory Affairs &amp; Quality, Straumann USA          E-Mail: jennifer.jackson@straumann.com          Telephone (978) 747-2509</p>
Date Prepared	14/Jul/2017
Prepared by	<p>Ana Carolina Martins Vianna          RA &amp; Compliance Manager, Institut Straumann AG          ana.vianna@straumann.com</p>
Product Code	DZE (21 CFR 872.3640) / NHA
Device Class	II
Classification Panel	Dental
Classification Name	Root-form endosseous dental implant (21 CFR 872.3640)
Common Name	Root-form endosseous dental implant
Proprietary name	Neodent Implant System – GM Line
Primary Predicate	K101945 - Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA
Reference Predicate Devices	<p>K150182 - Neodent Implant System – CM Drive line extension, JJGC Indústria e Comércio de Materiais Dentários SA          K153624 - Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA          K093027 – Straumann RC Temporary Abutments, Institut Straumann AG          K151455 – 3Shape Abutment Designer Software, 3Shape A/S          K130808 – Straumann Healing Abutments, Healing Caps and Closure Screws, Institute Straumann AG          K061804 – Zerion Alpha, Zerion Beta, ETKON International, GmbH</p>

## 5.1 Device Description

The GM Line of the Neodent Implant System (GM Line) consists in an expansion of the Neodent Implant System previously cleared under K101945, K150182 and K153624, presenting a new design of Morse taper implant-to-abutment interface trade named GM line.

The GM line comprises a range of endosseous dental implants as well as conventional and CAD/CAM abutments described as follows:

The GM Line dental implants are threaded, self-tapping, root form with a Morse taper implant-to-abutment interface with an internal hexagonal index exclusive to the GM line. They are made of titanium grade 4 conforming to ASTM F67. They are available in two types of surface treatment:

*NeoPoros*: rough surface created using an abrasive particle jet concept with controlled grain oxides, followed by acid etching creating uniform cavities in the implant surface.

*Acqua*: hydrophilic surface created from Neoporos rough surface that undergoes additional processing that renders hydrophilic surface.

### GM Titamax implants

The GM Titamax implants have cylindrical shape with double threads of pyramidal profile, rounded apex and are available in diameters of 3.5, 3.75 and 4.0 mm with lengths of 7, 8, 9, 11, 13, 15 and 17 mm, and in 5.0 mm diameter with lengths of 7, 8, 9, 11 and 13 mm. They are recommended for surgical intraoral installation in bone of type I or II.

### GM Helix implants

The GM Helix implants have a conical shape, double threads with trapezoidal profile, a rounded apex and are available in diameters of 3.5, 3.75, 4.0, 4.3 and 5.0 mm with lengths of 8, 10, 11.5, 13, 16 and 18 mm. They are recommended for surgical intraoral installation in bones types III or IV, or in bone of type I and II when using conical drills.

### GM Drive implants

The GM Drive implants have conical shape with double and progressive threads, cutting chambers in the counterclockwise direction, blade-shaped apical thread, rounded apex and are available in diameters of 3.5, 4.3 and 5.0 mm with lengths of 8, 10, 11.5, 13, 16 and 18 mm. They are recommended for surgical intraoral installation in bone of type III or IV.

The GM Line dental abutments are made of titanium alloy conforming to ASTM F136 and have a machined surface. The abutments are intended to be placed directly onto implants and are recommended according to the available interocclusal space, gingival height, and three-dimensional position of the implant. They can be used in immediate or conventional rehabilitation procedures on the maxilla or mandible.

### GM Cover Screws

The GM Cover Screws are devices for temporary use during the implant healing phase. They are available in two different heights: at the level of the platform (for use on implants placed at the

bone level) and with a gingival height of 2 mm (for use on implants placed up to 2 mm infraosseous). The GM Cover Screws are indicated for use during the osseointegration phase, on Neodent implants to be rehabilitated using the late loading technique. Cover Screws should remain intramucosal, impeding tissue grown over the platform of the implant. Cover Screws are placed out of occlusion.

#### GM Healings

The GM Healing Abutments are devices for temporary use. They are available in diameters of 3.3 and 4.5 mm and the following gingival heights: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm. They are indicated for maintenance of the soft tissue during the osseointegration phase of Neodent implant to be rehabilitated using the late loading technique. They can be used on the insertion of the Implant or re-opening surgery (second surgical phase). Healing Abutments are placed out of occlusion.

#### GM Micro Abutments / GM Mini Conical Abutment / GM Exact Mini Conical Abutment

They are intermediary prosthetic components to be installed onto GM implants to support the final prosthesis. They are provided in a rotational shape for the coupling with the prosthesis and in different gingival heights to match the variations in mucosal thickness. The GM Exact Mini Conical abutment is provided angled. They are indicated for screw-retained multiple-unit prostheses onto implants. The GM Micro Abutment, when used with the anti-rotational coping, is also indicated for single-tooth prosthesis.

#### GM Exact Abutments

GM Exact abutments are intermediary prosthetic components to be installed onto GM implants to support the final prosthesis. They are provided in an anti-rotational shape for the coupling with the prosthesis and are available in 3.5 and 4.8 mm of diameter and the following gingival heights: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm. They are indicated for screw-retained single-tooth prostheses onto implants.

#### GM Exact Click Universal Abutments (straight and angled)

GM Exact Click Universal abutments are intermediary prosthetic components to be installed onto GM implants to support the final prosthesis. They provided in an anti-rotational shape for the coupling with the prosthesis and in various angulation, prosthetic and gingival heights to match the variation in mucosal thickness. They are indicated for cemented-retained single-tooth prostheses onto implants.

#### GM Exact Titanium Base abutments

The Titanium Bases are intermediary prosthetic components to be installed onto GM implants to support the final prosthesis; the Titanium Base two-piece abutments used as a base when fabricating a CAD/CAM customized restoration. They are provided in an anti-rotational shape for the coupling with the prosthesis and are available in diameters of 3.5 and 4.5 mm and the following gingival heights: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm. The planning and milling of the customized superstructures must be made using the validated Dental Wings Operating System (DWOS) or 3Shape software. All digitally designed copings and/or crowns for use with the Titanium Bases are intended to be manufactured at a validated milling center. The limits for customization are stated in product IFU. The superstructure produced through CAD/CAM System will compose the second part of the two-piece abutment; the assembly becomes a

finished medical device after cementation on Titanium Base. They are indicated cemented-retained single-tooth prostheses onto implants.

#### GM Pro PEEK Abutment

GM Pro PEEK abutments are temporary intermediary prosthetic components to be installed onto the Implants to support the provisional prosthesis up to 6 months. They are composed of a customizable cylindrical body made of PEEK and a non-customizable base made of titanium alloy for an anti-rotational implant connection to GM implants. They are available in 4.5 and 6.0 mm of diameter and the following gingival heights: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm. Pro PEEK Abutments can be used before the installation of the final prosthesis to maintain, stabilize and shape the soft tissue (gum) during the healing phase. Pro PEEK Abutment must not be placed in occlusion when assembled with small diameter implants ( $\leq 3.75$  mm).

#### Protection Cylinders

The Protection Cylinders are prosthetic components with a tapered shape intended to be placed on abutments to protect them during the fabrication of the prosthesis and/or healing of the peri-implant tissues. They are available in models for attachment to abutments, mini conical abutments or micro abutments.

#### Coping Screws

The Coping Screws are prosthetic devices intended for coping fixation on the corresponding GM (screw-retained) abutment. They are available in two different models: one for fitting in GM Exact Abutments and another for fitting in GM Mini and Micro Abutments.

## **5.2 Indications for Use**

Indications for Use for GM implants and 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 GM Titanium Base abutments:

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 for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for GM Pro Peek Abutments:

The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.

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### 5.3 Technological Characteristics

The subject and the predicate devices have a range of dental implants and abutments with the same indication of providing solutions for teeth replacement, restoring chewing function.

The subject and predicate devices are based on the following same technological elements:

- Root-form implants intended to replace natural tooth root;
- Endosseous dental abutments to provide support for temporary or permanent restorations;
- Possibility of use in single or two-stage procedures, for single or multiple-unit restorations;
- Implants and conventional and CAD/CAM abutments made of the same material;
- Same sterilization methods and packaging for implants, conventional and CAD/CAM abutments.

The following technological differences exist between the subject and predicate devices:

- A new design of Morse taper implant-to-abutment interface is presented;
- A new design of implant thread was developed to fit in all types of bone quality;
- The subject temporary abutment is provided sterile by EO exposition whereas its predicate device is provided non-sterile for end-user sterilization.

In the end of this Section, a comparison between the features of subject device and its predicate devices is shown in a tabular format. The assessment of the differences is also included.

### 5.4 Performance data

The following performance data supports the substantial equivalence determination:

#### Biocompatibility testing

The implants are made of unalloyed titanium, Grade 4, conforming to ASTM F67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications* (UNS R50250, UNS R50400, UNS R50550, UNS R50700). The conventional and CAD/CAM abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications* (UNS R56401). The types of titanium are the same to that used for fabrication of the predicate devices cleared under K101945, K150182 and K153624. The subject devices undergo to the same manufacturing processes to the cited predicate devices.

The temporary abutments are made of PEEK. A chemical characterization of this material has been performed to identify leachable inorganic substances and extractable organic substances. Additionally, cytotoxicity analysis also has been performed.

The superstructures for titanium bases are made of zirconia, IPS e.max, Co-Cr and Lava Plus. Zirconia is conforming to ISO 13356 - *Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*, IPS e.max CAD (lithium disilicate) is conforming to ISO



6872 - *Dentistry - Ceramic Materials* and Co-Cr is conforming to ISO 22674 - *Dentistry - Metallic materials for fixed and removable restorations and appliances*. These raw materials are the same already cleared for the reference predicate devices under K153624. Lava Plus is an yttrium stabilized zirconium oxide (Y-TZP) and complies with the requirements of ISO 6872 *Dentistry - Ceramic Materials*. Cytotoxicity testing was performed for this raw material and showed no proliferation inhibition. Also, Lava Plus has been cleared by FDA per K072055 for manufacturing of dental restorations through CAD/CAM technique.

#### Mechanical testing

The strength of the system is demonstrated through fatigue testing performed according to ISO 14801 - *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants* and FDA document *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*. 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 Co<sup>60</sup> gamma irradiation at a nominal dose of 25 kGy (2.5 Mrad). Sterilization has been validated by the VD<sub>max</sub><sup>25</sup> method, 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*.

The subject abutments are sterilized by exposure to ethylene oxide (EO). Sterilization has been validated by the bioburden method, according to ISO 11135 *Sterilization of health care products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices*. EO sterilization residuals have been verified to be less than the maximum allowable limits as defined in ISO 10993-7 *Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals*.

The subject CAD/CAM superstructures are sterilized by moist heat (steam). The recommended sterilization has been validated according to ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*, and ISO/TS 17665-2 *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1*.

All methods achieve a Sterility Assurance Level (SAL) of 10<sup>-6</sup>.

The sterilization methods presented for the subject devices have been previously reviewed under K101945, K150182 and K153624.

### Shelf Life Testing

Shelf life testing for the Neodent Implant System was performed for both methods of sterilization, gamma irradiation and ethylene oxide exposure. Shelf life was determined through both accelerated and real time aging protocols according to ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier System for Medical Devices.

Table 1: General comparison between the subject and predicate devices.

	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATE DEVICES			EQUIVALENCE DISCUSSION
	Neodent Implant System – GM Line	Neodent Implant System (K101945)	Neodent Implant System (K150182)	Neodent Implant System (K153624)	Straumann RC Temp. Abutment (K093027)	
<b>Indications for Use</b>	<p><u>for GM implants and conventional abutments:</u> 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.</p> <p><u>for GM Titanium Base abutments:</u> 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 for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.</p> <p><u>for GM Pro Peek Abutments:</u> The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.</p>	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 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.	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 for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	The Straumann RC Temporary Abutments are indicated for use in Straumann RC Bone Level Implants for temporary restorations of single crowns and bridges for up to six months	<p><b>Equivalent</b></p> <p><u>Indications for Use for GM implants and conventional abutments:</u> The indications for use of the subject devices is included into the indications of the primary predicate devices.</p> <p><u>Indications for Use for GM Titanium Base abutments:</u> The indication for use is identical to the predicate K153624.</p> <p><u>Indications for Use for GM Pro Peek Abutments:</u> Both the indications of subject and predicate device (K093027) have the same intention to provide support to temporary restorations.</p>

	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATE DEVICES			EQUIVALENCE DISCUSSION
	Neodent Implant System – GM Line	Neodent Implant System (K101945)	Neodent Implant System (K150182)	Neodent Implant System (K153624)	Straumann RC Temp. Abutment (K093027)	
<b>Diameter(s)</b>	<u>Implants:</u> 3.5 to 5.0 mm  <u>Conventional abutments:</u> 3.3 to 4.8 mm  <u>CAD/CAM abutments:</u> 3.5 and 4.5 mm  <u>Temporary abutments:</u> 4.5 and 6 mm	<u>Implants:</u> 3.5 to 5.0 mm  <u>Conventional abutments:</u> 3.5 to 4.5 mm	<u>Implants:</u> 3.5 to 5.0 mm	<u>CAD/CAM abutments:</u> 3.5 and 4.5 mm	<u>Temporary abutments:</u> 4.5 mm	<b>Equivalent</b>  Subject device diameters are within the range of diameters of the predicate devices or larger. Larger diameters do not represent a worst case in terms of performance.
<b>Implants length</b>	8 to 18 mm	8 to 19 mm	18 mm	NA	NA	<b>Equivalent</b>  Subject implant lengths are within the range of the predicate devices.
<b>Implants types of threads</b>	Titamax Helix Drive	Titamax Alvim	Drive	NA	NA	<b>Equivalent</b>  Titamax model remains the same to that presented in K101945. Drive model presents changes when compared to K150182, however the changes do not affect dynamic fatigue performance. Helix model is new, however tests confirm that they have equivalent performances.
<b>Gingival Heights (of the abutments subject to masticatory load)</b>	0.8 to 5.5 mm	0.8 to 6.5 mm	NA	0.8 a 4.5 mm	Unknown	<b>Equivalent</b>  Subject device heights are included in the range of the predicate device heights and do not represent a worst case in terms of performance.

	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATE DEVICES			EQUIVALENCE DISCUSSION
	Neodent Implant System – GM Line	Neodent Implant System (K101945)	Neodent Implant System (K150182)	Neodent Implant System (K153624)	Straumann RC Temp. Abutment (K093027)	
<b>Material</b>	<u>Implants:</u> Titanium grade 4  <u>Conventional abutments:</u> Titanium alloy Ti-6Al-4V ELI  <u>CAD/CAM abutments:</u> Titanium alloy Ti-6Al-4V ELI  <u>Temporary abutments:</u> Titanium alloy Ti-6Al-4V ELI PEEK	<u>Implants:</u> Titanium grade 4  <u>Conventional abutments:</u> Titanium alloy Ti-6Al-4V ELI	<u>Implants:</u> Titanium grade 4	<u>CAD/CAM abutments:</u> Titanium alloy Ti-6Al-4V ELI	<u>Temporary abutments:</u> Titanium alloy (Ti-6Al-7Nb, TAN) PEEK (polyetheretherketone)	<b>Equivalent</b>  The subject and the predicate devices are made of the same type of raw material; the adequacy of the systems have been demonstrated via dynamic fatigue tests and biocompatibility assessment.
<b>Implant surface finish</b>	Neoporos Acqua	Neoporos	Neoporos Acqua	NA	NA	<b>Identical</b>
<b>Implant-to-Abutment Connection</b>	GM interface; 16° Morse taper with anti-rotational features.	CM interface; 11.5° Morse taper with anti-rotational features.	CM interface; 11.5° Morse taper with anti-rotational features.	CM interface; 11.5° Morse taper with anti-rotational features.	Morse taper interface with anti-rotational features	<b>Equivalent</b>  They are all Morse taper style connections and their performances were assessed by dynamic fatigue testing.
<b>Compatibility</b>	GM abutments are only compatible with GM implants	CM (Morse taper) lines of Neodent Implant System.	CM (Morse taper) abutments of Neodent Implant System.	CM (Morse taper) implants of Neodent Implant System.	Straumann implants	<b>Equivalent</b>  The Morse taper implant-to-abutment interfaces of Neodent and Straumann devices are not interchangeable. Their performances are assessed respecting the fixtures compatibility.

	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATE DEVICES			EQUIVALENCE DISCUSSION
	Neodent Implant System – GM Line	Neodent Implant System (K101945)	Neodent Implant System (K150182)	Neodent Implant System (K153624)	Straumann RC Temp. Abutment (K093027)	
<b>Sterility</b>	<p><u>Implants:</u> Delivered sterile via gamma irradiation.</p> <p><u>Conventional abutments:</u> Delivered sterile by EO exposure.</p> <p><u>CAD/CAM abutments:</u> Delivered sterile by EO exposure. To be sterilized by user after superstructure cementation, before placed in patient mouth (moist steam sterilization).</p> <p><u>Temporary abutments:</u> Delivered sterile by EO exposure.</p>	<p><u>Implants:</u> Delivered sterile via gamma irradiation.</p> <p><u>Conventional abutments:</u> Delivered sterile by EO exposure.</p>	<p><u>Implants:</u> Delivered sterile via gamma irradiation.</p>	<p><u>CAD/CAM abutments:</u> Delivered sterile by EO exposure. To be sterilized by user after superstructure cementation, before placed in patient mouth (moist steam sterilization).</p>	<p><u>Temporary abutments:</u> Delivered non-sterile; to be sterilized by user (moist steam sterilization).</p>	<p><b>Equivalent</b></p> <p>The sterilization methods remain the same amongst the different Neodent Implant Systems and, although the temporary abutments differs regarding sterilization, the Neodent temporary abutment is recommended to be customized chairside and thus does not need to be sterilized again before using.</p>
<b>CAD/CAM Restoration Angulation</b>	Up to 30°	NA	NA	Up to 30°	NA	<b>Identical</b>
<b>CAD/CAM Material of superstructure</b>	Zirconia IPS e-max CAD Co-Cr Lava Plus	NA	NA	Zirconia IPS e-max CAD Co-Cr	NA	<p><b>Equivalent</b></p> <p>The suitability of the additional raw material is proven through biocompatibility and performance tests.</p>
<b>CAD/CAM System</b>	DWOS or 3Shape	NA	NA	DWOS or 3Shape	NA	<b>Identical</b>

The following additional tables compare abutments intended to support conventional final restorations.

		GM Subject Abutments	Neodent Implant System (K101945)	EQUIVALENCE DISCUSSION
G M  E X A C T  A B U T M E N T S	<b>Indications for Use</b>	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.	<b>Equivalent</b>  The indications for use of the subject devices is included into the indications of the primary predicate devices.
	<b>Principle of operation</b>	To support final restorations when placed on implants.	To support final restorations when placed on implants.	<b>Identical</b>
	<b>Implant-to-Abutment Connection</b>	GM interface.	CM interface	<b>Equivalent</b>  Both are tapered connections. The performance of the new GM interface has been assessed by dynamic fatigue testing.
	<b>Implant-abutment anti-rotational feature</b>	With ("Exact")	Without	<b>Equivalent</b>  The anti-rotational feature is presented in other abutments of K101945.
	<b>Gingival Height</b>	0.8 to 5.5 mm	0.8 to 6.5 mm	<b>Equivalent</b>  Subject device heights are included in the range of the predicate device heights.
	<b>Angulation</b>	Straight	Straight	<b>Identical</b>
	<b>Material</b>	Titanium alloy Ti-6Al-4V ELI	Titanium alloy Ti-6Al-4V ELI	<b>Identical</b>
	<b>Surface</b>	Machined	Machined	<b>Identical</b>
	<b>Compatibility</b>	GM implants	CM implants of Neodent Implant System.	<b>Equivalent</b>  The Neodent lines are not interchangeable. Their performances are assessed respecting the fixtures compatibility.
	<b>Sterility</b>	Delivered sterile by EO exposure.	Delivered sterile by EO exposure.	<b>Identical</b>

		GM Subject Abutments	Neodent Implant System (K101945)	EQUIVALENCE DISCUSSION
G M I N I C O N I C A L A B U T M E N T S	<b>Indications for Use</b>	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.	<b>Equivalent</b> The indications for use of the subject devices is included into the indications of the primary predicate devices.
	<b>Principle of operation</b>	To support final restorations when placed on implants.	To support final restorations when placed on implants.	<b>Identical</b>
	<b>Implant-to-Abutment Connection</b>	GM interface.	CM interface	<b>Equivalent</b> Both are tapered connections. The performance of the new GM interface has been assessed by dynamic fatigue testing.
	<b>Implant-abutment anti-rotational feature</b>	Straight: without Angled: with ("Exact")	Straight: without Angled: with ("Exact") and without	<b>Identical</b>
	<b>Gingival Height</b>	Straight: 0.8 to 5.5 mm Angled: 1.5 to 3.5 mm	Straight: 0.8 to 6.5 mm Angled: 1.5 to 3.5 mm	<b>Equivalent</b> Subject device heights are included in the range of the predicate device heights.
	<b>Angulation</b>	Straight, 17° and 30°	Straight, 17° and 30°	<b>Identical</b>
	<b>Material</b>	Titanium alloy Ti-6Al-4V ELI	Titanium alloy Ti-6Al-4V ELI	<b>Identical</b>
	<b>Surface</b>	Machined	Machined	<b>Identical</b>
	<b>Compatibility</b>	GM implants	CM implants of Neodent Implant System.	<b>Equivalent</b> The Neodent lines are not interchangeable. Their performances are assessed respecting the fixtures compatibility.
<b>Sterility</b>	Delivered sterile by EO exposure.	Delivered sterile by EO exposure.	<b>Identical</b>	



		GM Subject Abutments	Neodent Implant System (K101945)	EQUIVALENCE DISCUSSION
G M M I C R O A B U T M E N T S	<b>Indications for Use</b>	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.	<b>Equivalent</b> The indications for use of the subject devices is included into the indications of the primary predicate devices.
	<b>Principle of operation</b>	To support final restorations when placed on implants.	To support final restorations when placed on implants.	<b>Identical</b>
	<b>Implant-to-Abutment Connection</b>	GM interface.	CM interface	<b>Equivalent</b> Both are tapered connections. The performance of the new GM interface has been assessed by dynamic fatigue testing.
	<b>Implant-abutment anti-rotational feature</b>	Without	Without	<b>Identical</b>
	<b>Gingival Height</b>	0.8 to 5.5 mm	1.5 to 3.5 mm	<b>Equivalent</b> The different gingival heights for straight abutments do not introduce a new worst case for fatigue performance.
	<b>Angulation</b>	Straight	Straight	<b>Identical</b>
	<b>Material</b>	Titanium alloy Ti-6Al-4V ELI	Titanium alloy Ti-6Al-4V ELI	<b>Identical</b>
	<b>Surface</b>	Machined	Machined	<b>Identical</b>
	<b>Compatibility</b>	GM implants	CM implants of Neodent Implant System.	<b>Equivalent</b> The Neodent lines are not interchangeable. Their performances are assessed respecting the fixtures compatibility.
<b>Sterility</b>	Delivered sterile by EO exposure.	Delivered sterile by EO exposure.	<b>Identical</b>	

		GM Subject Abutments	Neodent Implant System (K101945)	EQUIVALENCE DISCUSSION
G M E X A C T C L I C K U N I V E R S A L A B U T M E N T S	<b>Indications for Use</b>	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.	<b>Equivalent</b> The indications for use of the subject devices is included into the indications of the primary predicate devices.
	<b>Principle of operation</b>	To support final restorations when placed on implants.	To support final restorations when placed on implants.	<b>Identical</b>
	<b>Implant-to-Abutment Connection</b>	GM interface.	CM interface	<b>Equivalent</b> Both are tapered connections. The performance of the new GM interface has been assessed by dynamic fatigue testing.
	<b>Implant-abutment anti-rotational feature</b>	Straight: with ("Exact") Angled: with ("Exact")	Straight: with ("Exact") and without Angled: with ("Exact") and without	<b>Identical</b>
	<b>Gingival Height</b>	Straight: 0.8 to 5.5 mm Angled: 1.5 to 3.5 mm	Straight: 0.8 to 6.5 mm Angled: 1.5 to 3.5 mm	<b>Equivalent</b> Subject device heights are included in the range of the predicate device heights.
	<b>Angulation</b>	Straight, 17° and 30°	Straight, 17° and 30°	<b>Identical</b>
	<b>Material</b>	Titanium alloy Ti-6Al-4V ELI	Titanium alloy Ti-6Al-4V ELI	<b>Identical</b>
	<b>Surface</b>	Machined	Machined	<b>Identical</b>
	<b>Compatibility</b>	GM implants	CM implants of Neodent Implant System.	<b>Equivalent</b> The Neodent lines are not interchangeable. Their performances are assessed respecting the fixtures compatibility.
	<b>Sterility</b>	Delivered sterile by EO exposure.	Delivered sterile by EO exposure.	<b>Identical</b>

The following additional table compare abutments for short-term use intended to be used during the healing phase.

		GM Subject Abutments	Straumann Healing Abutments, Healing Caps and Closure Screws (K130808)	EQUIVALENCE DISCUSSION
H E A L I N G S / C O V E R S C R E W S / P R O T E C T I O N C Y L I N D E R S	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 single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Healing caps, closure screws and healing abutments are intended for use with the -Straumann® Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Customizable healing abutments made of PEEK are used for up to six months.	<b>Equivalent</b>  Both subject and predicate devices are indicated to restore missing teeth by using dental implant systems.
	Principle of operation	Conditioning the soft tissues and closing the implant/abutment interface during healing phase.	Conditioning the soft tissues and closing the implant interface during healing phase.	<b>Equivalent</b>  Protection cylinders are not part of the predicate device scope, however they have the same intention of use.
	Implant-to-Abutment Connection	GM interface.	NC Straumann interface	<b>Equivalent</b>  The different interfaces have no impact in the performance of the implantable system, since these devices are not placed under occlusion.
	Implant-abutment anti-rotational feature	NA	NA	NA
	Gingival Height	0,8 to 5,5 mm	Unknown	The different gingival heights have no impact in the performance of the implantable system, since these devices are not placed under occlusion.
	Angulation	Straight	Straight	<b>Identical</b>
	Material	Titanium alloy Ti-6Al-4V ELI	Titanium grade 4	<b>Equivalent</b>  Both are biocompatible materials and the different types of titanium have no impact in the performance of the implantable system, since these devices are not placed under occlusion.
	Surface	Machined and anodized	Machined and anodized	<b>Identical</b>
	Compatibility	GM implants	NC Straumann implants	<b>Equivalent</b>  The lines are not interchangeable. Their performances are assessed respecting the fixtures compatibility.

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		<b>GM Subject Abutments</b>	<b>Straumann Healing Abutments, Healing Caps and Closure Screws (K130808)</b>	<b>EQUIVALENCE DISCUSSION</b>
	<b>Sterility</b>	Delivered sterile by EO exposure.	Delivered sterile by gamma radiation.	<b>Equivalent</b> Both sterilization methods assure a SAL of 10 <sup>-6</sup> .

		GM Subject Abutments	Neodent Implant System (K101945)	EQUIVALENCE DISCUSSION
S C R E W S	<b>Indications for Use</b>	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.	<b>Equivalent</b> The indications for use of the subject devices is within the indications for use cleared for the predicate devices.
	<b>Principle of operation</b>	The screws are used to fix components of a dental implant system.	The screws are used to fix components of a dental implant system.	<b>Identical</b>
	<b>Implant-to-Abutment Connection</b>	GM interface	CM interface	<b>Equivalent</b> Different interfaces have their performances assessed via fatigue test.
	<b>Implant-abutment anti-rotational feature</b>	NA	NA	NA
	<b>Gingival Height</b>	NA	NA	NA
	<b>Angulation</b>	Straight	Straight	<b>Identical</b>
	<b>Material</b>	Titanium alloy Ti-6Al-4V ELI	Titanium alloy Ti-6Al-4V ELI	<b>Identical</b>
	<b>Surface</b>	Machined	Machined	<b>Identical</b>
	<b>Compatibility</b>	GM implants	CM implants	<b>Equivalent</b> The lines are not interchangeable. Their performances are assessed respecting the fixtures compatibility.
<b>Sterility</b>	Delivered sterile by EO exposure.	Delivered sterile by EO exposure.	<b>Identical</b>	

## **5.5 Conclusions**

The documentation submitted in this premarket notification demonstrates that the subject devices have comparable features and performance and, therefore, are substantially equivalent to the identified predicate devices.