December 19, 2019

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

Re: K192229
Trade/Device Name: Neodent Implant System - GM Titanium Base for Bridge
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 22, 2019
Received: November 25, 2019

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K192229

Device Name
Neodent Implant System - GM Titanium Base for Bridge

Indications for Use *(Describe)*
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.

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, Parana, Brazil 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person	Jennifer M. Jackson, MS Director of Regulatory Affairs, Straumann USA E-mail: jennifer.jackson@straumann.com Telephone (978) 747-2509
Date Prepared	09/Dec/2019
Preparer / Alternate Contact	Mariana Soares Hartmann Regulatory Affairs Analyst E-mail: mariana.hartmann@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Neodent Implant System – GM Titanium Base for Bridge
Common Name	Endosseous dental implant abutment
Classification Name	Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3630, Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K180536, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A
Reference Predicate Devices	K151157 – NC Straumann Variobase Abutment For Bars/Bridges, RC Straumann Variobase Abutment For Bars/Bridges, NNC

Straumann Variobase Abutment For Bars/Bridges, RN Straumann Variobase Abutment For Bars/Bridges, WN Straumann Variobase Abutment For Bars/Bridges, STRAUMANN USA, LLC.
K182620 - MRI Compatibility For Existing Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A

INDICATIONS FOR USE

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.

SUBJECT DEVICE DESCRIPTIONS

The GM Titanium Base for Bridge are prosthetic components to be installed onto GM implants to support the final prosthesis; the GM Titanium Base for Bridge is a two-piece abutment used as a base when fabricating a CAD/CAM customized restoration. The planning and milling of the customized superstructures should be made using the validated Dental Wings Operating System (DWOS) or 3Shape Software. All digitally designed copings and/or crowns for use with the GM Titanium Base for Bridge are intended to be manufactured as a validated milling center. The limits for customization are stated in the GM Titanium Base for Bridge Instructions for Use. The superstructure produced through the CAD/CAM System will compose the second part of the two-piece abutment; the assembly becomes a finished medical device after cementation on the GM Titanium Base for Bridge.

The main characteristics of the subject devices are the following:

- Intended for single use;
- Provided sterile via ethylene oxide gas;
- Manufactured of titanium alloy (Ti6Al4v-ELI) per ASTM F136;
- Conical format available in different diameters, height of cementable area and gingival height;
- Screw-retained;
- Provided in rotational (non-indexed) version supporting multi-unit restorations;
- Provided with an implant-to-abutment interface compatible with the GM implants of the Neodent Implant System.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
	K192229 Neodent Implant System – GM Titanium Base for Bridge JJGC Indústria e Comércio de Materiais Dentários S.A.	**K180536** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K151157** NC Straumann Variobase Abutment For Bars/Bridges, RC Straumann Variobase Abutment For Bars/Bridges, NNC Straumann Variobase Abutment For Bars/Bridges, RN Straumann Variobase Abutment For Bars/Bridges, WN Straumann Variobase Abutment For Bars/Bridges Straumann USA, LLC	
Indications for Use	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.	GM Helix 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. GM Exact Titanium Block for Medentika Holder: GM Exact Titanium Block for Medentika Holder is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. The GM Exact Titanium Block for Medentika Holder abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. All digitally designed abutments for use with the GM Exact Titanium Block for Medentika Holder are intended to be sent to Straumann for manufacture at a validated milling center.	Straumann® Variobase™ prosthetic components directly connected to the endosseous dental implants are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration (bridge or overdenture) can be cemented on the Straumann® Variobase™ prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. They may not be placed into occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated.	**Equivalent** The subject devices bring specific information regarding the restoration type indicated to be used with them but the general indications are the same for both subject and the GM Exact Titanium Base abutments of the predicate device.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
	K192229 Neodent Implant System – GM Titanium Base for Bridge JJGC Indústria e Comércio de Materiais Dentários S.A.	**K180536** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K151157** NC Straumann Variobase Abutment For Bars/Bridges, RC Straumann Variobase Abutment For Bars/Bridges, NNC Straumann Variobase Abutment For Bars/Bridges, RN Straumann Variobase Abutment For Bars/Bridges, WN Straumann Variobase Abutment For Bars/Bridges Straumann USA, LLC	
		GM Exact 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. Titanium Base C for GM Exact abutments: The Titanium Base C for GM Exact abutments is a titanium component that is placed over Neodent implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for single-tooth screw-retained restorations. All digitally designed copings and/or crowns for use with the Titanium Base C for GM Exact abutments are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.		
Implant-Abutment interface	GM	GM	N/A	**Same as Primary Predicate**

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	EQUIVALENCE DISCUSSION
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Design	Straight Conical upper portion Helical micro grooves in the cementable portion	Straight Cylindrical upper portion Helical micro grooves in the cementable portion	Straight Conical upper portion Helical micro grooves in the cementable portion	**Equivalent** The coronal design of the subject device is equivalent to that of the reference device K151157.
Reusable	No	No	No	**Same**
Diameter (Ø)	3.5, 4.5, and 5.5 mm	5.5 mm	3.3 mm	**Equivalent** The reference devices (K151157) have a minimum diameter of 3.3 mm which is similar to the subject devices. Dynamic fatigue testing was performed with the new worst-case design of the subject devices, the results indicate performance suitable for the intended use.
Gingival Height (mm)	0.8, 1.5, 2.5, 3.5, and 4.5	0.8, 1.5, 2.5, 3.5, 4.5, and 5.5	N/A	**Equivalent** **Subject devices are within the range established by the primary predicate.**
Maximum Angulation	30˚	30˚	30˚	**Same**
Abutment Height	4 mm	4 mm	3.5 – 5.2 mm	**Same as Primary Predicate**
Material	TAV (ASTM F136)	TAV (ASTM F136)	Ti-6Al-7Nb (TAN)	**Same as Primary Predicate**
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	Non-Sterile	**Same as Primary Predicate**

The subject devices and the primary predicate device (K180536) have the same Indications for Use, similar design, similar range of gingival height, same raw material and same sterilization method.

PERFORMANCE DATA

Dynamic fatigue test per ISO 14801 was performed to determine the fatigue strength for the worst-case implant construct assembled with GM Titanium Base for Bridge, according to FDA Guidance. The abutments were tested with three different restoration materials and all of them are in accordance with the acceptance criteria.
Torsion testing was performed to evaluate the Titanium Base Screws under static torsional loading. The results met the acceptance criteria.
Sterilization of the subject abutments via ethylene oxide gas using the overkill method has been validated according to the requirements of ISO 11135. A minimum Sterility Assurance Level (SAL) of 1×10^{-6} has been validated.
Ethylene oxide residuals have been assessed per ISO 10993-7. Residuals are within accepted limits.
Biological Safety Assessment guided by ISO 10993-1.
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.

CONCLUSION

The subject devices and the primary predicate devices K180536 have the same intended use, similar designs and technological characteristics, similar range of gingival height, same sterilization method and are made of the same materials. The data included in this submission demonstrate that the subject device is substantially equivalent to the predicate device.