December 5, 2019

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

Re: K191191
Trade/Device Name: Neodent Implant System - Temporary Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 1, 2019
Received: November 4, 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,

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)*
K191191

Device Name
Neodent Implant System - Temporary Abutments

Indications for Use *(Describe)*

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 - Temporary Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K191191 – 510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor	JJGC Indústria e Comércio de Materiais Dentários SA (dba Neodent) Av. Juscelino Kubitschek de Olivera, 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	04/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 – Temporary Abutments
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	K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.
Reference Predicate Devices	K093027 – STRAUMANN RC TEMPORARY ABUTMENTS, Straumann Manufacturing, INC.

K092814 – STRAUMANN DENTAL ABUTMENTS, Straumann Manufacturing, INC.
K103084 – Neodent Graft Screw, JJGC Indústria e Comércio de Materiais Dentários S.A.

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. The Neodent Implant System - Temporary Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months.

SUBJECT DEVICE DESCRIPTIONS

- Temporary Abutment for provisional restoration employed for up to 6 months;
- Intended for single use;
- Provided sterile via ethylene oxide gas;
- Constructed of titanium alloy (Ti6Al4v-ELI) per ASTM F136;
- Coronal geometry has grooves to facilitate bonding of acrylic material;
- Abutment is screw-retained;
- Coronal geometry contains channels to facilitate reduction of abutment height;
- Provided in anti-rotational and rotational versions supporting single and multi-unit restorations, respectively;
- Provided in multiple gingival heights;
- Implant-to-abutment interface compatible with GM implants of the Neodent Implant System.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

	SUBJECT DEVICE	**PRIMARY PREDICATE DEVICE**	**EQUIVALENCE DISCUSSION**
	Neodent Implant System	**K163194** Neodent Implant System – GM Line	
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. The Neodent Implant System - Temporary Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months.	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	**Equivalent** The subject device is a temporary abutment for use with GM implants, therefore only the first paragraph of the Indications of the primary predicate are relevant. The subject submission does not include Titanium Base Abutments or ProPEEK Abutments.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System	**K163194** Neodent Implant System – GM Line	
		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.	
Interface	GM	GM	**Same**
Design	Straight, cylindrical with retention rings	Straight and cylindrical	**Equivalent**
Reusable	No	No	**Same**
Gingival Height	0.8; 1.5; 2.5 and 3.5 mm	0.8; 1.5; 2.5; 3.5; 4.5 and 5.5 mm	**Equivalent** Subject devices within range established by predicate devices
Diameter (Ø)	3.5 and 4.5 mm	3.3 and 4.5 mm	**Equivalent**
Angulation	Straight	Straight, 17° and 30°	**Same** Subject devices are straight which is the same as the straight predicate devices.
Material	TAV (ASTM F136)	Implants: Titanium grade 4 Conventional abutments: Titanium alloy Ti-6Al-4V ELI CAD/CAM abutments: Titanium alloy Ti-6Al-4V ELI Temporary abutments: Titanium alloy Ti-6Al-4V ELI PEEK	**Same** Subject devices are the same material as the TAV predicate devices.
Duration of use (maximum)	180 days	Lifetime	**Equivalent** Subject devices within range established by primary predicate. Subject devices same as for reference predicates per K093027 and K092814
Sterilization Method	Ethylene Oxide to an SAL of $1x10^{-6}$	Ethylene Oxide to an SAL of $1x10^{-6}$	**Same**

The subject devices and the primary predicate device K163194 have equivalent Indications for Use, similar design, 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 Temporary Abutments for multi-unit restorations, according to FDA Guidance.

Torsion testing was performed to evaluate the GM Temporary Abutments Screws under static torsional loading.

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.

Accelerated and Real Time Aging tests were performed according to ASTM F1980. The Shelf Life of the subject devices is 5-years.

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 K163194 have the same intended use, similar designs and technological characteristics, 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.