January 29, 2021

JJGC Industria e Comercio de Materiais Dentarios SA
% Jennifer Jackson
Director of Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K202282
Trade/Device Name: Neodent Implant System - Zirconia Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 30, 2020
Received: December 31, 2020

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 Part 803) for devices or post-marketing 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.

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

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

Sincerely,

Andrew Steen
Assistant 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)*
K202282

Device Name
Neodent Implant System - Zirconia Implant System

Indications for Use *(Describe)*
Indications for Use for PEEK Abutment for Zirconia Implant System:

Neodent prosthetic abutments are indicated to be used on Neodent implants to provide support for prosthetic structures for up to 6 months. They can be used in single- or two-stage procedures and they are intended to be placed out of occlusion.

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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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	26/Jan/2021
Preparer / Alternate Contact	Mariana Soares Hartmann Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA E-mail: mariana.hartmann@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Neodent Implant System – Zirconia Implant System
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 Device	K201491 – Neodent Implant System – Zirconia Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A
Reference Device	K191191 – Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A
Reference Device	K182620 - MRI Compatibility for Existing Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A

INDICATIONS FOR USE

Neodent prosthetic abutments are indicated to be used on Neodent implants to provide support for prosthetic structures for up to 6 months. They can be used in single- or two-stage procedures and they are intended to be placed out of occlusion.

SUBJECT DEVICE DESCRIPTIONS

The subject device is a temporary abutment composed of PEEK with a titanium alloy fixation screw. The subject device is compatible with Neodent zirconia implant bodies with Zilock connection platform (K201491).

- Intended for single use;
- Provided sterile via Ethylene Oxide;
- The subject devices are manufactured of PEEK (high performance polymer – specific for dental use) and are provided along with a screw manufactured of titanium alloy according to ASTM F136 standard;
- ZiLock prosthetic interface with internal indexer;
- Cylindrical format with a passing hole to fixate the screw.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLES

Table 1. Technological Characteristic Comparison Table

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	K202282 Neodent Implant System - Zirconia Implant System PEEK CR Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line Pro PEEK Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K191191** Neodent Implant System GM Temporary Abutment for Crown JJGC Indústria e Comércio de Materiais Dentários S.A.	**Equivalence Discussion**
Indications for Use	Neodent prosthetic abutments are indicated to be used on Neodent implants to provide support for prosthetic structures for up to 6 months. They can be used in single- or two-stage procedures and they are intended to be placed out of occlusion.	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	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.	**Equivalent** Despite of the use of different words, the indications for use for the primary predicate devices and subject devices are the same. • Both are indicated for temporary support for a maximum period of time of 6 months; • Both can be used in one or two stage procedures; • Both can be used for immediate load.
Intended Use	The PEEK CR Abutment for Zirconia is a device indicated for use in the production of a single-unit provisional prosthesis on Zirconia Implants, installed in maxilla or mandible. It is supplied along with a screw for fixating the Abutment over the Implant.	The Temporary Abutment is used for temporary rehabilitation (up to 180 days) with screw-retained single-unit (anti-rotational abutment) or multi-unit (rotational abutment) prostheses.	The Temporary Abutment is used for temporary rehabilitation (up to 180 days) with screw-retained single-unit (anti-rotational abutment) or multi-unit (rotational abutment) prostheses.	**Equivalent** Subject devices and predicate devices are indicated for temporary use only.
Implant-Abutment interface	Straight internal connection indexing features (ZiLock)	GM Morse Taper	GM Morse Taper	**Equivalent** Subject devices and predicate devices present internal connection and are equipped with a rotational lock and an inner thread for fixation of the components.
Design	Cylindrical format with a passing hole to fixate the screw and anti-rotational implant-	Cylindrical format with a passing hole to fixate the screw and anti-rotational implant-	Cylindrical format with grooves to facilitate bonding of acrylic material and	**Equivalent**

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	
	K202282 Neodent Implant System - Zirconia Implant System PEEK CR Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line Pro PEEK Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K191191** Neodent Implant System GM Temporary Abutment for Crown JJGC Indústria e Comércio de Materiais Dentários S.A.	**Equivalence Discussion**
	to-abutment interface	to-abutment interface	circumferential channels to facilitate customization of abutment height. Presents anti-rotational implant-to-abutment interface	Subject devices and predicate devices present the same design and similar anti-rotational feature.
Reusable	No	No	No	**Identical** The subject devices and the predicate devices are indicated for single use.
Length (mm)	1.5; 2.5 mm	0.8; 1.5; 2.5; 3.5; 4.5; 5.5 mm	0.8; 1.5; 2.5; 3.5 mm	**Equivalent** Range of lengths for subject devices is within the range of lengths for the primary and reference predicate devices.
Diameter (Ø) (mm)	4.0; 4.5 mm	4.5; 6.0 mm	3.5; 4.5 mm	**Equivalent** Diameter of subject devices is within the range of diameters for the primary and reference predicate devices, so the subject devices do not represent a worst case in terms of performance.
Material	Body and base (implant-to-abutment interface): PEEK (high performance polymer – specific for dental use) Screw: Titanium Alloy (ASTM F136)	Body: PEEK (high performance polymer – specific for dental use) Base (implant-to-abutment interface): Titanium Alloy (ASTM F136) Screw: Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	**Equivalent** Both primary and reference predicate devices are made of the same raw materials. The main difference between the predicate devices and subject devices is the composition of the subject device body which is only PEEK.
Sterilization Method	Provided sterile via Ethylene Oxide to an SAL of $1x10^{-6}$	Provided sterile via Ethylene Oxide to an SAL of $1x10^{-6}$	Provided sterile via Ethylene Oxide to an SAL of $1x10^{-6}$	**Identical** Subject devices and predicate devices are provided sterile by the same sterilization method.

The subject devices have equivalent indications for use as the primary predicate devices. They also present an equivalent range of lengths as the primary and reference devices and equivalent range of diameter as the reference predicate devices, being contemplated within the range of lengths and diameter of the predicate devices.

Subject and predicate devices have implant-to-abutment interfaces with internal indexing. They present the same sterile barrier system and same sterilization method. The subject devices and primary predicate devices are manufactured of the same materials.

Overall, the subject devices are equivalent to the predicate devices as follows:

- same intended use,
- same operating principle,
- incorporate the same basic design,
- incorporate the same materials, and
- have same packaging and are sterilized using the same materials and processes

PERFORMANCE DATA

Biocompatibility

Biocompatibility for the subject devices was leveraged from the primary predicate device K163194. Ethylene oxide sterilization residuals according to ISO 10993-7 was also leveraged from the primary predicate device K163194.

Bench testing

The subject devices are not intended to be placed in occlusion and are not intended to correct angled implants. Therefore, there would be no forces focusing on them, so the company understands that the Dynamic Fatigue Test is not applicable.
MRI compatibility testing was leveraged from the reference device K182620.

Sterilization validation

The subject devices are sterilized by Ethylene Oxide, according to ISO 11135-1 via the over-kill method. The method achieved a Sterility Assurance Level of $1x10^{-6}$.
The Subject devices are not represented to be “pyrogen free”.
Bacterial Endotoxin Testing is leveraged from the primary predicate device K163194.

CONCLUSION

The subject devices and the predicate devices have equivalent intended use, design and technological characteristics. Equivalent range of overall dimensions and sterilization method. The data included in this submission demonstrate that the subject devices are substantially equivalent to the predicate devices.