August 13, 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: K210336
Trade/Device Name: Neodent Implant System - Zirconia Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 14, 2021
Received: July 16, 2021

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K210336

Device Name
Neodent Implant System - Zirconia Implant System

Indications for Use *(Describe)*
Indications for Use for Zirconia Implants:

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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.

Indications for Use for CR Abutment for Zirconia System:

The CR Abutment is an abutment placed over Neodent Zirconia Implants in order to provide support for prosthetic restorations, such as copings or crowns. It may be used for single-unit restorations that are cement-retained in esthetical areas over implants installed in maxilla or mandible.

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.

K210336
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	13/Aug/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 Endosseous dental implant abutment
Classification Name	Implant, Endosseous, Root-Form Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640 / 21 CFR 872.3630, Class II
Product Code	DZE/NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K201491 – Neodent Implant System – Zirconia Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A

Reference Predicate Devices	K151328 - PURE Ceramic Implants - Institut Straumann AG K101945 - Neodent Implant System – CM Line, JJGC Indústria e Comércio de Materiais Dentários S.A K182620 - MRI Compatibility For Existing Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A

INDICATIONS FOR USE

Indications for Use for Zirconia Implants:
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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.

Indications for Use for CR Abutment for Zirconia System:
The CR Abutment is an abutment placed over Neodent Zirconia Implants in order to provide support for prosthetic restorations, such as copings or crowns. It may be used for single-unit restorations that are cement-retained in esthetical areas over implants installed in maxilla or mandible.

SUBJECT DEVICE DESCRIPTIONS

- Intended for single use;
- Provided sterile via Ethylene Oxide;
- All devices of Zirconia Implant System are manufactured of Y-TZP (Yttrium-stabilized zirconium dioxide);
- The CR Abutment for Zirconia system is supplied along with a titanium alloy screw (ASTM F136);
- ZiLock prosthetic interface with internal indexer;
- Apically tapered implant with trapezoidal thread profile;
- Implant provided with sand-blasted, acid etched surface finish;
- The subject Implants are compatible with the Zirconia Bases (already cleared per market per K201491) and CR Abutments (subject of this submission);
- The subject CR Abutments are compatible with the Zirconia Implants 4.3 mm (already cleared per market per K201491) and Zirconia Implants 3.75 mm (subject of this submission).

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLES

Table 1. Technological Characteristic Comparison Table - Zirconia Implants

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	Equivalence Discussion
	Neodent Implant System - Zirconia Implant System Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K201491** Neodent Implant System - Zirconia Implant System Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K151328** PURE Ceramic Implants Institut Straumann AG	
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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can 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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.	The Straumann® PURE Ceramic Implant (Monotype) is indicated for restoration in single tooth gaps and in an edentulous or partially edentulous jaw. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. The Ø3.3 mm reduced diameter implants are recommended for central and lateral incisors only.	**Identical** The Indications for Use of the subject devices are the same as for the primary predicate devices.
Implant-Abutment interface	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)		**Identical** Subject devices and Primary Predicate devices present the same implant-abutment interface.
Design	Apically Tapered format Trapezoidal threads profile	Apically Tapered format Trapezoidal threads profile		**Identical** Subject devices and Primary Predicate devices present the same design.
Reusable	No	No	No	**Identical** The subject devices and the predicate devices are indicated for single use.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	
	Neodent Implant System - Zirconia Implant System Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K201491** Neodent Implant System - Zirconia Implant System Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K151328** PURE Ceramic Implants Institut Straumann AG	**Equivalence Discussion**
Length (mm)	10; 11.5; 13	8; 10; 11.5; 13	8; 10; 12; 14 mm	**Equivalent** Range of lengths for subject devices is within the range of lengths for the predicate devices.
Diameter (Ø) (mm)	3.75 mm	4.3 mm	3.3; 4.1 mm	**Equivalent** The diameter of the subject devices is smaller than the diameter of the primary predicate devices, but greater than the reference predicate devices. Dynamic Fatigue Testing were performed to ensure the system strength.
Material	Yttrium-stabilized zirconium dioxide (Y-TZP).	Yttrium-stabilized zirconium dioxide (Y-TZP).	Yttrium-stabilized zirconium dioxide (Y-TZP).	**Identical** Subject devices and predicate devices are manufactured of the same raw material.
Sterilization Method	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}.	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}.	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}.	**Identical** Subject devices and predicate devices are provided sterilized by the same method.

Table 2. Technological Characteristic Comparison Table – Zirconia CR Abutments

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System - Zirconia Implant System Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K201491** Neodent Implant System - Zirconia Implant System Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System – CM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	
Indications for Use	The CR Abutment is an abutment placed over Neodent Zirconia Implants in order to provide support for prosthetic restorations, such as copings or crowns. It may be used for single-unit restorations that are cement-retained in esthetical areas over implants installed in maxilla or mandible.	The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations, such as copings or crowns. It may be used for cement- or screw-retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	**Equivalent** The Indications for the subject devices are included within the scope of Indications for the primary predicate devices. Both are indicated to be placed over implants to support prosthetic restorations such as copings or crowns and the differences between the Indications for Use are due to the fact that the predicate device is digitally designed while the subject device is a stock abutment.
Implant-Abutment interface	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)	Cone morse internal connection	**Identical** Subject devices and Primary Predicate devices present the same implant-abutment interface.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System - Zirconia Implant System Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K201491** Neodent Implant System - Zirconia Implant System Implants JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101945** Neodent Implant System – CM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	
Design	Angulation: 0; 17° Gingival Height: 1.5; 2.5 mm Platform: NP; SP	Angulation: 0 Gingival Height: 1.5; 2.5 mm Platform: NP; SP	Angulation: 0, 17 and 30° Gingival Height: 1.5; 2.5 and 3.5 mm	**Equivalent** The angulation and gingival height of the subject devices are within the range of angulation and gingival height of the reference predicate device (K101945) the platform is identical of the primary predicate device.
Reusable	No	No	No	**Identical** The subject devices and the predicate devices are intended for single use.
Material	Abutment: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium alloy ASTM F136.	Abutment: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium alloy ASTM F136.	Abutment and Screw: Titanium alloy ASTM F136.	**Identical** The subject devices have the same material of construction as the primary predicate devices.
Sterilization Method	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	Provided sterile via Ethylene Oxide to an SAL of 10^{-6}	**Identical** The subject devices have the same sterilization method and same SAL as the predicate devices.

The subject implants have the same indications for use and an equivalent range of lengths as the primary predicate devices, being contemplated within the range of lengths of the predicate devices.

Subject and predicate implants have the same implant-to-abutment interface. Both present sand-blast and acid-etch surface finishes and same sterile barrier system. The subject implants are manufactured of the same materials and are sterilized using the same sterilization method as the primary predicate devices.

The subject CR Abutments have equivalent indications for use of the primary predicate devices and an equivalent range of gingival height and angulation as the reference predicate devices, being contemplated within the range of gingival height and diameter of the reference predicate devices. They also present the same sterilization method and are made of the same material as the primary predicate devices.

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

Representative samples of each of the subject devices was subjected to the following:

- Biological Safety Assessment guided by ISO 10993-1,
- Chemical characterization was performed per ISO 10993-18.

An assessment was made to define if new biocompatibility tests were needed or whether prior testing applies to the subject devices. The subject devices do not represent a new worst case and we are therefore relying on the results of the tests provided in K201491.

Mechanical testing

Dynamic fatigue test per ISO 14801 was performed to determine the fatigue strength for the dental implant system, according to FDA Guidance. The tested subject devices exhibit a level of performance equivalent to that reviewed for the predicate devices.

Torsion Test was performed to evaluate the Zirconia Implant System under static torsional loading.

Insertion test was performed to evaluate the insertion torque of the Zirconia Implant System when inserted into sawbones material representing bone type I, II, III and IV.

SEM images made after fatigue loading test were included to demonstrate that the subject devices present similar wear in the implant inner thread compared to the Zirconia Implant (K201491).

Screw torque testing was performed with torque application and visual analysis before and after use to assess whether the torque would damage the items. No visible failure was identified after applying torque

and removing items from the implant. The subject screws are considered equivalent to those already cleared per K201491.

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 $1x10^{-6}$.

An assessment was made to determine if the subject devices represent new worst-cases for sterilization validation and since they do not represent a new worst-case, they are being adopted into the already the same sterilization validation method already cleared under K201491.

The Subject devices are not represented to be "pyrogen free".

Bacterial Endotoxin Testing are performed on representative samples selected and tested based upon the raw material, manufacturing processes and sterilization process, according to ANSI/AAMI ST72:2011, Bacterial Endotoxins – Test Methods, Routine Monitoring and Alternatives to Batch Testing. The obtained results were <0,05 EU/device.

MR Conditional Labeling

The MR Conditional Labeling was leveraged from K182620.

Shelf Life

Product and package stability have been validated per ASTM F1980. The subject device's shelf life was determined to be 5 years.

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.