DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 16, 2016

JJGC Indústria e Comércio de Materiais Dentários SA
% Jennifer Jackson
Senior Manager, Regulatory Affairs & Quality Management
Straumann USA, LLC
60-100 Minuteman Road
Andover, Massachusetts 01810

Re: K160964
Trade/Device Name: Neodent Implant System - Titanium Bases For Cerec
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 11, 2016
Received: August 18, 2016

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 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 yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160964

Device Name

Neodent Implant System - Titanium Bases for CEREC

Indications for Use *(Describe)*

The Titanium Base for CEREC 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 Neodent Titanium Base for CEREC 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.

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)

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510(k) Summary

Submitter	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 on behalf of: JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Olivera, 3291 Curtiba, Parana, BRAZIL 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person	Jennifer Jackson, MS Head of Quality and Regulatory, Straumann USA Telephone (978) 747-2509
Date Prepared	15/Sep/2016
Prepared by	Ana Carolina Martins Vianna Regulatory Affairs Analyst, JJGC Indústria e Comércio de Materiais Dentários SA avianna@neodent.com.br
Product Code	NHA (21 CFR 872.3630)
Device Class	II (21 CFR 872.3630)
Classification Panel	Dental
Classification Name	Endosseous dental implant abutment (21 CFR 872.3630)
Common Name	Endosseous dental implant abutment
Proprietary name	Neodent Implant System – Titanium Bases for CEREC
Primary Predicate	K151324 - Straumann® Variobase™ for CEREC Abutments, Institut Straumann AG
Reference Predicates	K153624 - Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA K111421 - Sirona Dental CAD/CAM System

5.1 Device Description

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The Titanium Base for CEREC consists of a two-piece abutment, where the titanium base is a pre-manufactured abutment that will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment) that composes the final abutment.

The Titanium Base for CEREC 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* and are provided in a 4.65 mm prosthetic platform diameter and seven gingival heights (0.8, 1.5, 2.5, 3.5, 4.5, 5.5 and 6.5 mm), all having a 4.7 mm prosthetic height. They also feature:

- cylindrical shape
- hexagonal indexing at the apical end of the Morse taper connection
- indexing guide in the cementable portion for coping fitting

Figure 1: Image of a Titanium Base for CEREC abutment

The CAD/CAM customized superstructure that composes the final abutment must be designed and milled through the Sirona Dental CAD/CAM System, according to the prosthetic planning and patient clinical situation.

The Titanium Base for CEREC is provided sterile by Ethylene Oxide and steam sterilization is recommended after the cementation of the customized superstructure on the Titanium Base for CEREC.

The Titanium Base for CEREC is compatible with the following devices:

Dental implants

All Neodent dental implants having Morse taper implant-to-abutment interface (CM line) cleared under K101945, K123022, K133592, K150182 and K150199.

Raw material blanks

- InCoris Zi (ZrO2) by Sirona Dental Systems GmbH, L size blanks, cleared under K123664;
- IPS e.max CAD Abutments Solutions ($LiSi_2$) by Ivoclar Vivadent AG, L size blanks, cleared under K132209.

Software

Sirona Dental CAD/CAM System, by Sirona Dental Systems GmbH, cleared under K111421.

No change has been made in the software, its settings or configuration, as well as any modification in the workflow. Sirona inLab software (version 3.65) or Sirona CEREC® Software (version 4.2) are to be used to design the prosthesis structure according to the previous prosthetic planning. Therefore, the customers are required to use the device models (3D models) and the workflow defined and validated by Sirona through K111421, according to the Instruction for Use of Titanium Base for CEREC

Instruments

- Neodent screwdrivers (class I – exempt devices)
- Sirona scanbodies (class I – exempt devices)

Note: The raw material blanks, the scanbodies and the software are not subject of this submission and are not supplied by Neodent. They are identical to the compatible materials used for predicate devices K151324.

5.2 Indications for Use

The Titanium Base for CEREC 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 Neodent Titanium Base for CEREC 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.

5.3 Technological Characteristics

Both the subject and the reference devices have the same indication of providing support for prostheses. All devices are pre-manufactured (stock) abutments made of titanium alloy design to be used as a base when fabricating a CAD/CAM customized superstructure and are compatible with the same CAD/CAM System and blocks of raw material. A clinician or dental laboratory equipped with the Sirona Dental CAD/CAM System will design and mill the customized superstructure, which composes the final medical device after the bonding to the Titanium Base for CEREC.

The subject devices differ from the primary predicate devices cleared under K151324 only in the portion of implant connection, which is specific for each manufacturer. The cementable portion is identical and compatible with the Sirona Dental CAD/CAM System and the blocks of raw material.
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 subject device Titanium Base for CEREC abutment is made of titanium alloy conforming to ASTM F136, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications* (UNS R56401). This material is commonly used for endosseous dental implant abutments and is the same material used for Neodent Implant System components previously cleared in K150367. Therefore, no new biocompatibility testing has been performed.

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 Neodent Titanium Base for CEREC does not present a new worst case when compared to the reference device Neodent Titanium Base cleared under K153624. So, no new fatigue tests have been performed, and the same tests presented in K153624 were used to demonstrate the substantial equivalence.

Software Verification and Validation Testing

The recommended software was considered as a “moderate” level of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator. Therefore, the subject Titanium Base for CEREC was verified and validated with respect to its functionality and design using the Sirona validated workflow. The recommended CAD/CAM System is the same used for the primary predicate device and the validation performed was based on the validation presented by the manufacturer of the primary predicate device.

Note: Neodent makes no changes to the software, its settings or configuration, as well as no modification in the workflow defined and validated by Sirona per K111421. The Sirona software is recommended because of the compatibility of its existing 3D models with the subject devices.

Sterilization validation

The subject Titanium Base for CEREC abutments are provided sterilized by exposure to ethylene oxide (EO). Sterilization has been validated 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* using Annex B – *Conservative determination of lethal rate of the sterilization process – Overkill approach.*

Following fabrication of the superstructure for the Titanium Base, the assembled (cemented) final abutment must be sterilized before use 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/TR 17665-2 *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1*.

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Both methods achieve a Sterility Assurance Level (SAL) of 10^{-6}.

Clinical data

No clinical data has been submitted, referenced, or relied upon to demonstrate substantial equivalence.

Table 2: Comparison between the subject and predicate devices.

	SUBJECT DEVICE	**PRIMARY DEVICES**	**REFERENCE PREDICATE**		
	Neodent Implant System - Titanium Base for CEREC®	Straumann® Variobase® for CEREC® **(K151324)**	Neodent Implant System **(K153624)**	Sirona Dental CAD/CAM System **(K111421)**	**EQUIVALENCE DISCUSSION**
Indications for Use	The Titanium Base for CEREC 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 Neodent Titanium Base for CEREC 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.	The Straumann® Variobase® for CEREC® are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for CEREC® abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase® for CEREC® abutments are to be designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.	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 Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restoration. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetic in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646) Nobel Biocare Branemark (K022562) Friadent Xive (K013867) Biomet 3i Osseotite (KK980549) Astra Tech Osseospeed (K091239) Zimmer Tapered Screw-Vent (K061410) Straumann SynOcta (K061176) Biomet 3i Certain (K014235) Nobel Biocare Active (K071370)	**Equivalent** The basic indication of providing support for prostheses is identical. All devices are CAD/CAM abutment design to be used as a base when fabricating a customized superstructure. The subject devices are compatible with the same CAD/CAM System as the primary predicate device.

	SUBJECT DEVICE	PRIMARY DEVICES	REFERENCE PREDICATE		
	Neodent Implant System - Titanium Base for CEREC®	Straumann® Variobase® for CEREC® **(K151324)**	Neodent Implant System **(K153624)**	Sirona Dental CAD/CAM System **(K111421)**	**EQUIVALENCE DISCUSSION**
Abutment Diameter(s)	4.65 mm	4.5 to 7.0 mm	3.5 and 4.5 mm	Unknown	**Equivalent** Subject devices diameter is within the range of diameters for the primary predicate devices and does not represent a worst case in terms of performance.
Implant-to-Abutment Connection	Morse taper (CM) interface	RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit), and RC (Regular CrossFit)	Morse taper (CM) interface	Unknown	**Equivalent** The implant-to-abutment interfaces of Neodent and Straumann devices are not interchangeable but it is identical to the reference predicates of K153624.
Compatibility	Morse taper (CM) implant lines of Neodent Implant System.	Straumann implant lines, as indicated by the implant-to-abutment interfaces.	Morse taper (CM) implant lines of Neodent Implant System.	Unknown	**Equivalent** The implant-to-abutment interfaces of Neodent and Straumann devices are not interchangeable but it is identical to the reference predicates of K153624.
Mode of attachment	Screw-retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained	**Equivalent** Subject device mode of attachment is more restrictive and is within the scope of the primary predicate device's mode of attachment.

	SUBJECT DEVICE	PRIMARY DEVICES	REFERENCE PREDICATE		
	Neodent Implant System - Titanium Base for CEREC®	Straumann® Variobase® for CEREC® **(K151324)**	Neodent Implant System **(K153624)**	Sirona Dental CAD/CAM System **(K111421)**	**EQUIVALENCE DISCUSSION**
Restoration Angulation(s)	Up to 20°	Up to 20°	Up to 30°	Up to 20°	**Equivalent** The restoration angulation is identical among the devices that use Sirona Dental CAD/CAM System and only differs for the reference device K153624 that is compatible with other software.
Abutment Height(s)	4.7 mm	4.7 mm	4.0 mm	Unknown	**Equivalent** Subject device height is identical to that of the primary predicate device; differs from the reference device, which uses other CADCAM Systems.
Material of abutment	Titanium-aluminum-vanadium alloy Ti-6Al-4V	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-aluminum-vanadium alloy Ti-6Al-4V	Titanium-aluminum-vanadium alloy Ti-6Al-4V	**Equivalent** The subject and reference devices are made of the same titanium alloy; the titanium alloy of the primary predicate device differs, but the strength of the materials is demonstrated via dynamic fatigue testing. Also, all materials are shown to be biocompatible.

	SUBJECT DEVICE	PRIMARY DEVICES	REFERENCE PREDICATE		
	Neodent Implant System - Titanium Base for CEREC®	Straumann® Variobase® for CEREC® **(K151324)**	Neodent Implant System **(K153624)**	Sirona Dental CAD/CAM System **(K111421)**	**EQUIVALENCE DISCUSSION**
Material of superstructure	Zirconia IPS e-max CAD	Zirconia IPS e-max CAD PMMA	Zirconia IPS e-max CAD Co-Cr	Zirconia	**Equivalent** The range of materials cleared for use with the primary predicate and reference devices is within the scope of materials indicated for the subject devices.
Patient-specific design	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures	**Identical**
Manufacturing work-flow	Sirona Dental CAD/CAM System	Sirona Dental CAD/CAM System	Straumann validated workflow at Straumann Milling Center	Sirona Dental CAD/CAM System	**Equivalent** The subject device manufacturing work-flow is the same of the primary predicate device workflow.
Sterility	Delivered sterile by EO exposure. To be sterilized by user after superstructure cementation, before placed in patient mouth.	Delivered non-sterile. ; To be sterilized by user after superstructure cementation, before placed in patient mouth.	Delivered sterile by EO exposure. To be sterilized by user after superstructure cementation, before placed in patient mouth.	Delivered non-sterile; to be sterilized by user.	**Equivalent** Although Neodent and predicate devices are sold to the customers in different sterilization condition, all final abutments must be sterilized by steam before be placed in patient mouth.
Sterilization by end user	Moist steam sterilization	Moist steam sterilization	Moist steam sterilization	Moist steam sterilization	**Identical**

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.