



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 15, 2016

JJGC Indústria e Comércio de Materiais Dentários SA
c/o Ms. Jennifer Jackson
Head of Quality and Regulatory
Straumann USA, LLC
60-100 Minuteman Road
Andover, Massachusetts 01810

Re: K153624

Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 15, 2016
Received: March 17, 2016

Dear Ms. 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,

Erin I. Keith -S

Erin I. Keith, M.S.

Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153624

Device Name

Neodent Implant System

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 for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter Straumann USA, LLC
60 Minuteman Road
Andover, MA 01810
Registration No.: 1222315
Owner/Operator No.: 9005052

on behalf of:

JGC 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 M. Jackson, MS
Head of Quality and Regulatory, Straumann USA
Telephone (978) 747-2509

Date Prepared 15/April/2016

Prepared by Ana Carolina Martins Vianna
Regulatory Affairs Analyst, JGC 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

Primary Predicate K150367 - Neodent Implant System, JGC Indústria e Comércio de
Materiais Dentários SA

Reference Predicates K120822 - Straumann® CARES® Variobase™ Abutments, Institut
Straumann AG
K142890 - Straumann® CARES® Variobase™ Abutments, Institut
Straumann AG

Device Description

This submission includes the Titanium Base abutments (two-piece hybrid abutments) and the superstructures that compose the final abutment (the second part of the two-piece abutment).

The Titanium Base abutments are provided in two prosthetic platform diameters (3.5 and 4.5 mm), each in five gingival heights (0.8, 1.5, 2.5, 3.5 and 4.5 mm). They have a Morse taper implant-to-abutment interface and an additional hexagonal indexing feature at the apical end of the Morse taper connection. The surface is as-machined, without any type of treatment

surface. The Titanium Base abutment is an intermediary prosthetic component between the implant and prosthesis; a CAD/CAM abutment design to be used as a base when fabricating a coping, crown or bridge superstructure. It is a stock abutment, previously cleared per K150367. The subject abutments are compatible with Neodent dental implants having Morse taper (CM) implant-to-interface cleared under K101945, K123022, K133592, K150182 and K150199.

The purpose of this submission is to expand the range of materials allowed in fabricating the superstructure, adding Co-Cr and IPS e.max® CAD materials to the previously cleared portfolio.

A dental laboratory equipped with an appropriate CAD system, will design a customized superstructure or restoration made of zirconia, IPS e.max® CAD or Co-Cr. Each patient-specific superstructure is individually prescribed by the clinician. The minimum wall thickness of the structure is variable depending on the material, according to the table below. The maximum angling of the structure should not exceed 30°. The taper of the structure should not exceed 6°. In the case of a structure angled at the height of the cementable portion starting at the emergence profile (prosthetic height), it should not exceed 10 mm for the Morse Taper.

Material	Minimum thickness (mm)
CoCr	0.3
Zirconia	0.5
IPS e.max	0.6

The planning of the customized superstructures must be made using the validated Dental Wings Operating System (DWOS) or 3Shape software. 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

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.

Technological Characteristics

The Titanium Base abutment is a two-piece abutment consisting of a pre-manufactured (stock) abutment made of titanium alloy conforming to ASTM F136 - *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications* (UNS R56401), and a customized superstructure made of ceramics (zirconia or IPS e.max® CAD) or Co-Cr. A dental laboratory equipped with an appropriate CAD system, will design a customized superstructure or restoration, which must be milled at a Straumann validated milling center.

The following table shows a comparison among the features of subject device and its predicate and reference devices. The assessment of the differences is also included.

	SUBJECT DEVICE	PRIMARY PREDICATE	
	Neodent Implant System	Neodent Implant System (K150367)	EQUIVALENCE DISCUSSION
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 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 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.	Equivalent The basic indication of providing support for prostheses is identical. Additional wording was added to the indications to support the titanium base abutments manufacturing process. The subject device and primary predicate have slightly different Indications for Use language. However, the difference in language does not change the intended use or substantial equivalence.
Abutment Diameter(s)	3.5 and 4.5 mm	3.5 and 4.5 mm	Identical
Implant-to-Abutment Connection	Morse taper (CM) interface	Morse taper (CM) interface	Identical
Compatibility	Morse taper (CM) implant lines of Neodent Implant System.	Morse taper (CM) implant lines of Neodent Implant System.	Identical
Mode of attachment	Screw-retained or cement retained	Screw-retained or cement retained	Identical
Restoration Angulation(s)	Up to 30°	Up to 30°	Identical
Gingival Height(s)	0.8, 1.5, 2.5, 3.5 and 4.5mm	0.8, 1.5, 2.5, 3.5 and 4.5mm	Identical
Material of abutment	Titanium-aluminum-vanadium alloy Ti-6Al-4V	Titanium-aluminum-vanadium alloy Ti-6Al-4V	Identical

	SUBJECT DEVICE	PRIMARY PREDICATE	
	Neodent Implant System	Neodent Implant System (K150367)	EQUIVALENCE DISCUSSION
Material of superstructure	Zirconia Co-Cr IPS e-max CAD	Zirconia	Equivalent Addition of IPS e.max CAD and CoCr materials does not change the Indications For Use. These materials are used widely for dental restorations, including with the Straumann Variobase devices identified as reference devices to this submission.
Sterility	Delivered sterile by EO exposure. To be sterilized by user after the coping cementation, before placed in patient mouth.	Delivered sterile by EO exposure. To be sterilized by user after the coping cementation, before placed in patient mouth.	Identical
Sterilization by end user	Moist steam sterilization	Moist steam sterilization	Identical

Performance data

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include engineering analysis, and dimensional analysis. Testing submitted or referenced in this submission in support of a substantial equivalence determination is as follows:

- Mechanical testing was performed on the Titanium Base abutments including the superstructures 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* dated May 12, 2004
- Ethylene Oxide sterilization validation per ISO 11135
- Steam sterilization validation per the ISO 17665 series standards
- Biocompatibility is supported as the material of the titanium base is identical to the company's own predicate. In addition, the materials for construction of the superstructure are identical to Straumann reference predicates and manufactured at a Straumann validated milling center.
- Clinical data were not submitted in this premarket notification.

Conclusions

Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices and do not raise new issues of safety and effectiveness when uses as labeled.