DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 13, 2015

Jjgc Industria E Comercio De Materiais Dentarios S
c/o Mr. Kevin Thomas
Paxmed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K150367
Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 27, 2015
Received: May 28, 2015

Dear Mr. Thomas:

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,

for 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

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)*
K150367

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.

PreFace Abutment is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. PreFace Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations.

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.

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510(k) Summary

JJGC Indústria e Comércio de Materiais Dentários SA

Neodent Implant System

July 13, 2015

ADMINISTRATIVE INFORMATION

Manufacturer Name	JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Oliveira, 3291 - CIC Curitiba, Paraná, 81270-200, Brazil Telephone: +55 41 2169 4058 Fax: +55 41 2169 1043
Official Contact	Jacson Cambruzzi Head of Quality and Regulatory Affairs
Representative/Consultant	Kevin A. Thomas, PhD PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 (858) 792-1235 Fax +1 (858) 792-1236 Email kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Neodent Implant System
Common Name	Endosseous dental implant abutment
Classification Name	Endosseous dental implant abutment
Classification Regulation	21 CFR 872.3630, Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED 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.

PreFace Abutment is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. PreFace Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations.

DEVICE DESCRIPTION

The purpose of this submission is to expand the Neodent Implant System components cleared under K101945, K123022, and K133592; these submissions included dental implants with a Morse taper abutment interface, mating abutments, abutment screws, and other associated components. This submission includes the Titanium Base Abutment, 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). Titanium Base is an abutment to be used as a base when fabricating a zirconia superstructure. This submission also includes the PreFace Abutment in two overall (milling) diameters of 11.5 and 15.8 mm. The PreFace Abutment with overall (milling) diameter of 15.8 mm is only used to mill an angled abutment.

PreFace is an abutment to be used in fabricating a full custom abutment in titanium alloy. After milling the minimum wall thickness for the PreFace must be no less than 0.4 mm, and the emergence profile diameter must be at least 3.3 mm. The maximum limit for angulation is 30°, and the maximum gingival height is 6 mm from the implant platform. In the case of an angled abutment, the cementable height from the emergence profile (prosthetic height) must not exceed 6 mm. The total height of the abutment (above the implant-abutment connection platform) must be no greater than 14.2 mm and no shorter than 4 mm. The range for the abutment body diameter (above the implant-abutment connection platform) is 3.3 mm to 8.5 mm. The implant interface must remain intact and cannot be modified.

The subject 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 (UNS R56401).* The subject abutments are compatible with Neodent dental implants having the Morse taper interface cleared in K101945, K123022 and K133592.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility, engineering analysis, and dimensional analysis. Mechanical testing was performed on the Titanium Base and PreFace abutments according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*. Sterilization validation testing was performed 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 17665-2 *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1*. Clinical data were not submitted in this premarket notification.

EQUIVALENCE TO MARKETED DEVICE

Neodent Implant System is substantially equivalent in indications and design principles to the following legally marketed predicate devices:
K120822, Straumann® CARES® Variobase™ Abutments, Institut Straumann AG;
K052272, Straumann C.A.R.E.S. Titanium Abutment, Institut Straumann AG;
K133421, Straumann® Magellan™ Abutment System, Institut Straumann AG;
K133592, Neodent Implant System, Neodent USA, Inc.;
K123022, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA.; and
K101945, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA.

The primary predicate device for the Titanium Base abutment is K120822. The primary predicate device for the PreFace abutment is K052272. The reference predicate devices are K133421, K133592, K123022, and K101945. A comparison of the technological characteristics of the subject device and the primary predicate devices K120822 and K052272 is provided in the following table.

	Subject Device	**Primary Predicate Devices**	
Comparison	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K150367	Institut Straumann AG Straumann® CARES® Variobase™ Abutments K120822	Institut Straumann AG Straumann C.A.R.E.S. Titanium Abutment K052272
Indications for Use	Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. PreFace Abutment is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. PreFace Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations.	The Straumann® CARES® Variobase™ Abutment is a two-piece dental abutment consisting of the Straumann® Variobase™ Abutment and the Straumann® CARES® Variobase™ Coping which is intended to be placed onto Straumann dental implants to provide support for prosthetic reconstruction such as crowns and bridges. Straumann® CARES® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. The Straumann® CARES® Variobase™ Coping polycon® ae in combination with the Straumann® Variobase™ Abutment is indicated for temporary (up to 180 days) dental restoration of a Straumann dental implant.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The Straumann C.A.R.E.S. Titanium Abutment is indicated for cemented restorations. The abutment can be used in single tooth replacements and multiple tooth restorations.
Abutment Characteristics			
Design	Titanium Base and CAD/CAM Blank	Titanium Base	CAD/CAM Blank
Prosthesis Attachment	Screw-retained Cement-retained	Cement-retained	Cement-retained

	Subject Device	Primary Predicate Devices	
Comparison	JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System K150367	Institut Straumann AG Straumann® CARES® Variobase™ Abutments K120822	Institut Straumann AG Straumann C.A.R.E.S. Titanium Abutment K052272
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Abutment Diameter	Titanium Base: 3.5 and 4.5 mm PreFace: 11.5 and 15.8 mm (milling diameter)	3.3 - 6.5 mm	3.3 - 6.5 mm
Abutment Angle	Up to 30°	Up to 30°	Up to 30°
Abutment/ Implant Interface	Indexed	Indexed, non-indexed	Indexed, non-indexed
Abutment Material	Ti-6Al-4V	Ti-6Al-7Nb	Ti-6Al-7Nb
Abutment Screw Material	Ti-6Al-4V	Ti-6Al-7Nb	Ti-6Al-7Nb

The subject device and the primary predicate devices have substantially equivalent indications for use, including providing support for customized prosthetic restorations.

The subject Titanium Base abutments are substantially equivalent in design, function, size, and material to the Straumann CARES Variobase Abutments cleared in K120822. All are titanium alloy bonding bases for CAD/CAM zirconia superstructures. The scanning and designing software used for the zirconia superstructure is the Straumann CARES System (K120822). Final fabrication of the abutment will be done at the Straumann Milling Center. The subject PreFace abutments are substantially equivalent in design, function, size, and material to the Straumann C.A.R.E.S. Titanium Abutment cleared in K052272. Both are abutment blanks for CAD/CAM fabrication of a custom titanium alloy abutment. Each has a precision implant-abutment interface compatible with specific implant systems. The scanning and designing software used for the subject PreFace abutment is the Straumann CARES System (K052272). Final fabrication of the abutment will be done at the Straumann Milling Center.

Minor differences in the technological characteristics of the subject device and primary predicate devices include the option for screw-retained prosthesis attachment, the range of (finished) abutment diameters, the provision of only indexed implant interfaces for the subject devices, and slight differences in the device materials (Ti-6Al-4V for the subject devices and Ti-6Al-7Nb for the primary predicate devices).

Mechanical test results demonstrated that the strengths of subject Titanium Base and PreFace abutments are equal to or greater than that of predicate abutments in K120822 and K133421, respectively.

CONCLUSION

Overall, the subject device has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is to be sterilized using the same processes.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.