JJGC Industria e Comercio de Materiais Dentarios S.A. April 20, 2018
Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K173902
Trade/Device Name: Neodent Implant System - GM Line
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 22, 2018
Received: March 22, 2018

Dear Kevin 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -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)*

K173902

Device Name

Neodent Implant System – GM Line

Indications for Use *(Describe)*

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.

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

K173902

Neodent Implant System – GM Line

JJGC Indústria e Comércio de Materiais Dentários SA

April 18, 2018

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Neodent Implant System – GM Line
Common Name	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

PREDICATE DEVICE INFORMATION

The primary predicate device is K163194. The reference predicate devices are K101207, K121843, and K133696.

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 procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the Neodent Implant System – GM Line components cleared under K163194, which included dental implants with a Morse taper abutment interface (called Grand Morse, or GM), mating abutments, abutment screws, and other associated components. This submission includes the GM Exact Co-Cr Abutment for Crown and the GM Equator Attachment. The subject device components mate exclusively with the GM implants cleared in K163194.

The GM Exact Co-Cr Abutment for Crown is provided in three sizes to fit the prosthetic diameter sizes of the GM implants cleared in K163194. The subject device abutments consist of a Co-Cr alloy component that interfaces directly to the implant and a cylinder of polyoxymethylene (POM) for fabrication of a cast prosthesis by a burn-out technique. The subject device abutments are provided in three (3) sizes to match the various platforms of the mating GM implants: 3.5/3.75 mm platform diameter, 4.0/4.3 mm platform diameter, and 5.0/6.0 mm platform diameter. The subject device abutments are for single-unit prosthetic restorations only. The final prosthetic restoration may be cement-retained or screw-retained.

The GM Equator Attachment abutments are straight, ball-type abutments for the attachment of full or partial overdentures. GM Equator Attachment abutments are provided in five gingival heights (1.5, 2.5, 3.5, 4.5, and 5.5 mm), and may be used with all GM implant diameter sizes cleared in K163194.

The subject device GM Exact Co-Cr abutments are made of Co-Cr alloy conforming to ASTM F1537, with mating abutment screws made of titanium alloy conforming to ASTM F136. The GM Equator Attachment abutments made of titanium alloy conforming to ASTM F136 with a TiN coating identical to the TiN coating cleared in K133696.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence include biocompatibility testing of the subject device GM Exact Co-Cr Abutment for Crown according to ISO 10993-5, ISO 10993-12 and ISO 10993-18. Non-clinical data relied upon to demonstrate substantial equivalence with regard to biocompatibility of titanium alloy components were incorporated by reference to K163194 and K133696. Sterilization validation testing of subject devices was performed according to ISO 17665-1, ISO TS 17665-2, ISO 11135, and ISO 10993-7. Sterile barrier shelf life testing was performed on real time aged samples (referenced from K163194) and included seal strength testing, helium leak detection, and sterility testing of the package contents. Bacterial endotoxin testing was performed using methods described in AAMI / ANSI ST72. Clinical data were not submitted in this premarket notification.

EQUIVALENCE TO MARKETED DEVICES

JJGC Indústria e Comércio de Materiais Dentários S.A. submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.;

K101207, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A.;

K121843, NP-Cast Abutment System, OSSTEM Implant Co., Ltd.; and

K133696, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A.

A comparison of the Indications for Use and the technological characteristics of the subject device and the primary predicate device K163194 is provided in the following table.

Comparison	Subject Device	Primary Predicate Device
	Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	K163194 Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.
Indications for Use Statement	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.	Indications for Use for GM implants and conventional abutments: 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. Indications for Use for GM Titanium Base abutments: 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. Indications for Use for GM Pro Peek Abutments: 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.
Product Code	NHA	DZE, NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Design		
Implant Design	Not applicable	Threaded root-form implants, 3 thread designs; Internal Morse taper abutment connection
Implant Diameter		Various, 3.5 mm to 5.0 mm
Implant Length		Various, 7 mm to 18 mm
Abutment Design	GM Exact Co-Cr Abutment for Crown: Component for cast-to fabrication GM Equator Attachment: Ball-type for partial or full overdentures	Healing; temporary; conventional 1-piece, 2-piece, CAD-CAM
Gingival Height	GM Exact Co-Cr Abutment for Crown: 1.0 mm GM Equator Attachment: 1.5, 2.5, 3.5, 4.5, 5.5 mm	0.8 mm to 5.5 mm
Implant-Abutment Platform Diameter	Exact Co-Cr Abutment for Crown: To match GM implant diameters 3.5/3.75, 4.0/4.3, and 5.0/6.0 GM Equator Attachment: Fits all GM implants	To match implant diameters
Prosthesis Attachment	Exact Co-Cr Abutment for Crown: Cement-retained, screw-retained GM Equator Attachment: Ball-type for partial or full overdentures	Cement-retained and screw-retained
Restoration	Exact Co-Cr Abutment for Crown: Single-unit GM Equator Attachment: Multi-unit	Single-unit and multi-unit
Abutment Angle	None (straight 0° only)	None (straight 0°), 17°, 30°
Abutment-Implant Interface	Exact Co-Cr Abutment for Crown: Morse taper (GM Line) GM Equator Attachment: Morse taper (GM Line)	Morse taper (GM Line)
Materials		
Abutment	Exact Co-Cr Abutment for Crown: Co-Cr-Mo alloy, ASTM F1537 GM Equator Attachment: Ti-6Al-4V alloy, ASTM F136, with TiN coating	Ti-6Al-4V alloy, ASTM F136; PEEK
Abutment Screw	Exact Co-Cr Abutment for Crown: Ti-6Al-4V alloy, ASTM F136 GM Equator Attachment: Not applicable	Ti-6Al-4V alloy, ASTM F136

Comparison	Subject Device	Primary Predicate Device
	Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	K163194 Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.
How Provided		
Sterility/Sterilization	Exact Co-Cr Abutment for Crown: Non-sterile GM Equator Attachment: Sterile by ethylene oxide exposure	Abutments: Sterile by ethylene oxide exposure
Usage	Single-patient, single-use	Single-patient, single-use

The primary predicate device K163194 is for substantial equivalence of the subject device abutment-implant interface design. The subject device abutments have the identical implant interface design and are to mate exclusively with the Neodent GM implants cleared in K163194. The subject device abutments and abutments cleared in K163194 are provided in straight (0°) designs with internal hex prosthetic indexing and titanium alloy abutment screws. The differences between the subject device abutments and the abutments cleared in K163194 are the addition of the cast-to design and the Co-Cr alloy material.

The reference predicate device K101207 is for substantial equivalence of the design of the cast-to, UCLA-type abutment. K10107 included cast-to, UCLA-type abutments consisting of a titanium alloy component that interfaces directly to the implant and a POM burn-out sleeve for fabrication of a cast abutment. The differences between the subject device abutments and the abutments cleared in K101207 are the implant interface and the Co-Cr alloy material.

The reference predicate device K121843 is for substantial equivalence of the cast-to, UCLA-type abutment design consisting of a Co-Cr alloy component that interfaces directly to the implant and a POM burn-out sleeve for fabrication of a cast abutment. The subject device abutments and the abutments cleared in K121843 include Morse taper connections with internal hex indexing. The primary difference between the subject device abutments and the abutments cleared in K121843 is the implant interface.

The Indications for Use Statements for the subject device and primary predicate device K163194 are similar, with the language that the subject device abutments are for support of prosthetic restorations. The intended use of the subject device abutments is similar to that of the abutments in each of the predicate devices. The slight differences in wording among the Indications for Use Statements for the subject device and the predicate devices reflects the fact that the predicate submissions include components, such as CAD/CAM abutments, that are not included in the subject submission. The differences do not affect the intended use with dental implants for rehabilitation of the edentulous maxilla or mandible.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of the same or similar materials. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.