FEB 2 4 2014

510(k) Summary

JJGC Indústria e Comércio de Materiais Dentários SA

Neodent Implant System

November 15, 2013

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 1003 Fax: +55 41 2169 1043
Official Contact	Jafte Carneiro Fagundes da Silva Chief Compliance, Legal and Regulatory Officer – CCLRO
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 Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640
Product Code	DZE NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED 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. Multiple tooth applications may be rigidly splinted.

DEVICE DESCRIPTION

The purpose of this submission is to expand the Neodent Implant System components cleared under K101207, which included dental implants with an external hex abutment interface. The external hex additions include Titamax Smart, Titamax Smart EX, and Drive Smart implants that are provided with a new implant mount that can be used as a temporary abutment. Additional straight, angled and ball-type abutments with external hex interfaces are also included in this submission.

All of the subject device external implants are threaded, self-tapping, root form, endosseous dental implants with a grit blasted and acid etched endosseous surface. All implants have a smooth machined collar on the transgingival surface. The Titamax Smart implants are provided in five endosseous thread diameters (3.3, 3.75, 4.0, 4.5, 5.0 mm), three platform diameters (3.3, 4.1, 5.0 mm), and five overall lengths (9, 11, 13, 15, 17 mm). The Titamax Smart EX implants are provided in two endosseous thread diameters (3.75, 4.0 mm), one platform diameter (4.1 mm), and six overall lengths (9, 11, 13, 15, 17, 19 mm). The Drive Smart implants are provided in three endosseous thread diameters (3.5, 4.3, 5.0 mm), three platform diameters (3.3, 4.3, 5.0 mm), and five overall lengths (8, 10, 11.5, 13, 16 mm). All implants are made from commercially pure titanium conforming to ASTM F67.

This submission includes the following abutments: the Smart Mount in three platform diameters (3.3, 4.1/4.3, 5.0 mm); Conical Abutments (platform diameter 3.3 mm); Angled Mini Conical abutments angled 17° or 30°, in four platform diameters (3.3, 4.1, 4.3, 5.0 mm), and gingival heights from 2 mm to 5 mm; SF Universal Post abutments (platform diameter 4.5 mm); Angled Post abutments angled 17° or 30°, in four platform diameters (3.3, 4.1, 4.3, 5.0 mm), and gingival heights from 2 mm to 5 mm; and Equator Attachment abutments for overdentures or partial dentures in three platform diameters (4.1, 4.3, 5.0 mm) and gingival heights from 2 mm to 5 mm. All abutments are made from titanium alloy conforming to ASTM F136.

EQUIVALENCE TO MARKETED DEVICE

Neodent Implant System is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K101207

JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K101945

JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K123022

The implants of the subject Neodent Implant System have similar designs and dimensions, use the same materials, and have the same surface as those cleared under K101207, K101945, and K123022. The abutments of the subject Neodent Implant System have similar designs and are made from the same material as those cleared under K101207, K101945, and K123022.

The subject device has similar packaging and is sterilized using the same materials and processes as described in K101207, K101945, and K123022.

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility, engineering analysis, dimensional analysis, static and dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*. Fatigue testing demonstrated the subject device to be equivalent to the predicate devices.

Clinical data were not submitted in this premarket notification.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and diameter, height and angle of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy. The device is safe and effective for its intended use and performs as well as or better than the predicate devices.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 24, 2014

JJGC Indústria e Comércio de Materiais Dentários SA
C/O Dr. Kevin A. Thomas, PhD
Regulatory Affairs
PaxMed International, Limited Liability Company
12264 El Camino Real, Suite 400
San Diego, CA 92130

Re: K133510
Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE
NHA
Dated: January 28, 2014
Received: January 29, 2014

Dear Dr. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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.
Acting 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: K133510

Device Name: Neodent Implant System

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. Multiple tooth applications may be rigidly splinted.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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