510(k) Summary

MAY 17 2013

JJGC Indústria e Comércio de Materiais Dentários SA
Neodent Implant System

K123022

May 6, 2013

ADMINISTRATIVE INFORMATION

Manufacturer Name:	JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Oliveira, 3291 – CIC Curitiba – PR – CEP, 81270-200, Brazil Telephone: +55 41 2169 4071 Fax: +55 41 2169 4041
Official Contact	Daniel Lecuona General Manager
Representative/Consultant	Allison C. Komiyama, Ph.D. Linda K. Schulz, BSDH, RDH PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: akomiyama@paxmed.com lschulz@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.

Titamax WS implant is indicated for a delayed loading protocol.

The Facility implant is indicated for replacement of maxillary lateral incisors, mandibular incisors or retention of overdentures.

DEVICE DESCRIPTION

The Neodent Implant System implants included in this submission are threaded, self-tapping, root form, endosseous dental implants with a Morse taper abutment interface. They are designed to provide support for prosthetic teeth to restore chewing function. They are made of commercially pure titanium or titanium alloy, with a surface that is grit blasted and acid etched. In addition, multiple abutments made of titanium alloy are provided for each implant for both cement-retained and screw-retained prostheses. The CM Drive implant comes in three diameters (3.5, 4.3 and 5.0 mm), each in five lengths (8.0, 10.0, 11.5, 13.0, and 16.0 mm). The Titamax WS implant design comes in three diameters (4.0, 5.0, and 6.0 mm) with corresponding platform diameters. The 4.0 mm diameter Titamax WS implant comes in one length (6.0 mm). The 5.0 and 6.0 mm diameter Titamax WS implants come in two lengths (5.0 and 6.0 mm). The Facility implant design comes in one diameter (2.9 mm), and in five lengths (8, 10, 12, 14, and 16 mm). All abutments included in this submission are straight and have a Morse taper connection.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent to the following predicate devices:
K101945, K070601, K080598, K073343, K092594, K081653, K092035, K050712, and K010185

The Neodent Implant System expands the currently cleared system to include new designs of implants and their corresponding cement- or screw-retained abutments. The implants of the subject Neodent Implant System have a similar design, identical material and identical surface as those cleared under K101945. The new Titamax WS implant is similar in indications, design and dimensions to the Bicon devices cleared in K092035, K050712, and K010185. The new Facility implant is similar in indications, design and dimensions to the Intra-Lock devices cleared in K070601 and K080598, the Ace Surgical Supply devices cleared in K073343 and K092594, and the IMTEC Corporation devices cleared in K081653. The abutments of the subject Neodent Implant System have a similar design and identical material as those cleared under K101945.

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: engineering analysis, dimensional analysis and comparative surface area analysis. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Clinical data were not submitted in this premarket notification.

CONCLUSIONS

The subject device and the predicate devices have the same intended use, have the same technological characteristics, and are made of the same 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.

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

May 17, 2013

JJGC Indústria e Comércio de Materiais Dentários SA
C/O Allison C. Komiyama Ph.D.
Senior Regulatory Specialist
PaxMed International, Limited Liability Company
11234 El Camino Real, Suite 200
SAN DIEGO CA 92130

Re: K123022
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: April 18, 2013
Received: April 19, 2013

Dear Dr. Komiyama:

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,

Anthony D. Watson, B.S., M.S., M.B.A.
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: K123022

Device Name: Neodent Implant System

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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)

Susan Runner, DDS, MA

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=13000879
Date: 2013.05.10 14:44:43 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123022