K103084

FEB 14 2011

510(k) Summary

JJGC Indústria e Comércio de Materiais Dentários SA

Neodent Graft Screw

January 25, 2011

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 4046
Official Contact:	Daniel Lecuona
Representative/Consultant:	David J. Collette, MD Kevin A. Thomas, PhD PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130, USA Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: dcollette@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Neodent Graft Screw
Common Name:	Screw, Fixation, Intraosseous
Classification Régulation:	21 CFR 872.4880
Product Code:	DZL
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

This product is an implantable device used for fixation of bone blocks for the regeneration of bone in the oral cavity. The product is intended for temporary use only.

DEVICE DESCRIPTION

The Neodent Graft Screw (Graft Screw) is an implantable device used for fixation of bone blocks in dental surgery. The design of the Graft Screw includes a tapered, self-drilling tip and a cruciform head. The Graft Screw is available in various lengths, thread diameters and head diameters.

PREDICATE DEVICES

Salvin Dental Specialties Fixation Screw from Salvin Dental Specialties, Inc. (K073342)
STOMA Bone Block Screw, Steel from Storz am Mark GmbH (K080430)
Bone Block Fixation Set from Straumann USA, Inc. (K050515)

TECHOLOGICAL CHARACTERISTICS

The design, materials and functional characteristics of the Neodent Graft Screw are substantially the same as those in the predicate devices. The subject and predicate devices are made of biocompatible alloys commonly used for implantable devices. The subject and predicate devices encompass the same range of physical dimensions, including thread form, thread pitch, diameters and lengths. Each is described as self-drilling, self-tapping and/or self-cutting.

NON-CLINICAL TESTING

Non-clinical testing consisted of material specification and engineering design review.

CLINICAL TESTING

Not applicable to this device.

CONCLUSION

Based on information presented in this submission, we conclude that the Neodent Graft Screw is substantially equivalent to predicate devices with the same intended use and technological features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JJGC Indústria e Comércio de Materiais Dentários SA
C/O Dr. David J. Collette
Regulatory Affairs
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

FEB 14 2011

Re: K103084
Trade/Device Name: Neodent Graft Screw
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: January 24, 2011
Received: January 26, 2011

Dear Dr. Collette:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K103084

Device Name: Neodent Graft Screw

Indications for Use:

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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)

Page 1 of __

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control and Dental Devices
510(k) Number: K103084