K102769

FEB 23 2011

510(k) Summary

JJGC Indústria e Comércio de Materiais Dentários SA

Neodent Implant for Orthodontic Anchorage

September 23, 2010

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
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Neodent Implant for Orthodontic Anchorage
Common Name:	Implant, Endosseous, Orthodontic
Classification Regulation:	21 CFR 872.3640
Product Code:	OAT
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

This product is a surgical device in the form of a temporary screw used as an aid in orthodontic movement procedures.

DEVICE DESCRIPTION

The Neodent Implant for Orthodontic Anchorage (Neodent Anchor) is a device that is temporarily implanted into the bone to provide a fixed anchorage point for various orthodontic tooth movements. The single-piece design features a self-drilling threaded shaft for bony fixation and a low profile head having a conical transmucosal segment and points for attachment of various appliances to facilitate orthodontic movement of teeth.

EQUIVALENCE TO MARKETED DEVICE

JJGC Indústria e Comércio de Materiais Dentários SA demonstrated that, for the purposes of FDA's regulation of medical devices, the Neodent Implant for Orthodontic Anchorage (Neodent Anchor) is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices:

ORLUS Mini Screw from Ortholution Company, Limited, cleared under K082838,

Aarhus Anchorage System from Medicon E.G., cleared under K041527, and

Syntec Orthodontic Mini Screws from Syntec Scientific Corporation, cleared under K090476.

The intended use, design, materials and functional characteristics of the Neodent Anchor and the predicate devices are substantially the same. All are indicated for temporary fixed anchorage of orthodontic appliances and accessories used in the movement of teeth. The basic design of each consists of a threaded shaft for bone anchorage and a contoured head for attachment of various orthodontic appliances and accessories. The subject and predicate devices are made of Ti-6Al-4V titanium alloy, a well-proven material for implantable devices. The subject and predicate devices encompass the same range of physical dimensions, and are packaged in similar materials and sterilized using similar methods.

Overall, Neodent Implant for Orthodontic Anchorage 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 sterilized using the same materials and processes.

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 Industria e Comercio de Materiais Dentarios SA
C/O David Collette, MD
Paxmed International, LLC
11234 El Camino Real Suite 200
San Diego, California 92130

FEB 23 2011

Re: K102769
Trade/Device Name: Neodent Implant for Orthodontic Anchorage
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: February 14, 2011
Received: February 15, 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,

Anthony D. 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 (if known): K102769

Device Name: Neodent Implant for Orthodontic Anchorage

Indications for Use:

This product is a surgical device in the form of a temporary screw used as an aid in orthodontic movement procedures.

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

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