K110548

510k Summary

JUL 29 2011

July 22, 2011

Trade Name: Juell OSI O-ball Abutment Dental Implant

Common Name: o-ball implant

Material: ASTM F136 Ti6Al4V

Company Contact:

John Roderick, Operations Manager
Juell Dental
2401 N. Commerce
Ardmore, OK 73401
(580) 798-4414

Device Description

The JUELL OSI O-Ball Abutment Dental Implant is available with a gingival collar in four diameters: 3.0mm, 3.5mm, 4.0mm and 4.5mm. The JUELL OSI O-Ball Abutment Dental Implant is available in thread lengths ranging from 10mm to 18mm. The implant is manufactured from ASTM F136 Ti6Al4V. The threaded surface is blasted with particulate media to increase the surface area.

Indications for Use

The OSI O-ball Abutment implant is a self-tapping titanium threaded screw indicated for long term intra-bony fixation of upper and lower dentures in edentulous cases. These devices will permit immediate splinting and ability and short-term fixation of failing crown and bridge installations, for full or partial edentulism. They can be used in the anterior regions of the maxillary and mandibular arches and are indicated for immediate loading when there is good primary stability and appropriate occlusal load.

Testing

Fatigue was conducting according to a mofified ISO 14801 on the 3.0mm implant with the exception of the angle the implant was held being adjusted to 15° and the loading point being on the o-ball causing the length from the bone level to be 5mm and the length from the holding line to be 8mm.

Substantial Equivalence

	OSI o-ball	Nobel Active o-ball (k102436)	Champion (k091182)
Diameter (mm)	3.0,3.5,4.0,4.5	3.3	4, 4.5
Length (mm)	10,13,15,17,18	10, 11.5, 13,15	10 to 16
Implant head shape	o-ball	o-ball	o-ball
Indications for use	The OSI O-ball Abutment implant is a self-tapping titanium threaded screw indicated for long term intra-	The Nobel Active 3.0 implant is indicated for use in the treatment of missing lateral incisors or the mandibular central	The Champions Implants MIMI 1-Piece Precision Implant is intended to support single or multi-unit

	bony fixation of upper and lower dentures in edentulous cases. These devices will permit immediate splinting and ability and short-term fixation of failing crown and bridge installations, for full or partial edentulism. They can be used in the anterior regions of the maxillary and mandibular arches and are indicated for immediate loading when there is good primary stability and appropriate occlusal load.	and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The Nobel Active 3.0 Implants may be put in immediate function provided that stability requirements detailed in the manual are satisfied.	restorations in both long-term and temrporary applications throughout the maxillary and mandibular arches. The MIMI 1-Piece Precision Implant is indicated for immediate loading when there is good primary stability and an appropriate occlusal load. The MIMI 1-Piece Precision Implants have diameters from 4,0 to 4,5mm and are available in length of 10 to 16mm.
Material	Ti6Al4V	Ti6Al4V	Ti6Al4V
Sterilization	Delivered sterile	Delivered sterile	Delivered sterile
Procode	Dze	dze	dze
Screw pitch	Between Imtec fine and coarse	Self-tapping compression threads	Microthreads with cutting flute and coarse compression threads
Screw surface	Blasted and clean	Sandblasted and acid etched	Blasted and etched
Fatigue testing	Tested to modified ISO 14801 sucessfully	Tested according to the guidance document sucessfully	No testing information in the 510k summary

The materials, surface treatment, and design are similar and show Juell o-ball abutments to be substantially equivalent to the predicate devices. The indications for use is similar to those of the predicate devices so the Juell o-ball abutments are substantially equivalent to the predicate devices. Both Juell o-ball abutment implants and the predicate devices tested in fatigue successfully, so Juell o-ball abutment implants are substantially equivalent to the predicate devices.

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

Juell Dental
C/O Ms. Angela Blackwell
Senior Consultant
Biologics Consulting Group
2401 North Commerce
Ardmore, Oklahoma 73401

JUL 29 2011

Re: K110548
Trade/Device Name: OSI o-Ball Abutment Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 22, 2011
Received: July 25, 2011

Dear Ms. Blackwell:

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): K110548

Device Name: OSI o-ball abutment implants

Indications for Use:

The OSI O-ball Abutment implant is a self-tapping titanium threaded screw indicated for long term intra-bony fixation of upper and lower dentures in edentulous cases. These devices will permit immediate splinting and ability and short-term fixation of failing crown and bridge installations, for full or partial edentulism. They can be used in the anterior regions of the maxillary and mandibular arches and are indicated for immediate loading when there is good primary stability and appropriate occlusal load.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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