K091878

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SECTION 5 – 510(k) SUMMARY

Submission Correspondent

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OCT - 6 2009

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www.osseolink.com/

Date Prepared

May 11, 2009

Trade Name

OsseoLink Dental Implant System

K091878

273

Regulation Name(s)

1. Endosseous Dental Implant

2. Endosseous Dental Implant Abutment

Regulation Number(s)

1. 872.3640

2. 872.3630

Classification Name(s)

1. Implant, Endosseous, Root-Form

2. Abutment, Implant, Dental, Endosseous

Product Code(s)

1. DZE

2. NHA

Classification Panel

Dental Devices

Regulatory Class

Class II

Device Description

The OsseoLink Dental Implant System is an endosseous type artificial tooth replacement system that is intended for use in prosthetic dentistry to support restorations that resemble a tooth or group of teeth.

Intended Use

Implants

OsseoLink dental implants are indicated for use in partially or fully edentulous

mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The OsseoLink Dental System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. The placement of individual Ø 3.5 mm diameter implants in the molar region in not recommended.

Prosthetic Abutments, Cover Screws & Healing Abutments

OsseoLink prosthetic abutments are intended for use with OsseoLink dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. OsseoLink cover screws are used when submerged healing is desired in two stage implant surgery procedures. OsseoLink healing abutments are used at the time of implant placement when non-submerged (i.e., single-stage) surgical placement is indicated or following the uncovering of an implant when the two-stage protocol is followed.

Predicate Device(s)

1. Sulzer Dental, Inc. – *Screw Vent & Tapered Screw Vent* – (K013227)
2. Nobel Biocare, LLC – *Groovy Implants* – (K050258)

Safety and Effectiveness

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the OsseoLink Dental Implant System and the predicate devices do not raise any questions regarding its safety and effectiveness. The OsseoLink system, as designed and manufactured, is as safe and effective as the predicate devices and therefore is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Global Implant Solutions, L.L.C.
C/O Mr. Stuart R. Goldman
Emergo Group, Incorporation
1705 South Capital of Texas Highway, Suite 500
Austin, Texas 78746

OCT - 6 2009

Re: K091878
Trade/Device Name: OsseoLink Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 21, 2009
Received: September 23, 2009

Dear Mr. Goldman:

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name

OsseoLink Dental Implant System

Indications for Use

Implants

OsseoLink dental implants are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The OsseoLink Dental System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. The placement of individual Ø 3.5 mm diameter implants in the molar region in not recommended.

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Kevin Mulvey for MSN

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K091878