K093595

SECTION 5 – 510(k) SUMMARY

JAN - 4 2011

Submission Correspondent

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Date Prepared

January 4, 2011

Trade Name

CeraRoot Implant System

K093595

Regulation Name

Endosseous Dental Implant

Regulation Number

872.3640

Classification Name

Implant, Endosseous, Root-Form

Product Code(s)

DZE

Classification Panel

Dental Devices

Regulatory Class

Class II

Predicate Device(s)

1. Nobel Biocare AB – *Zirconia Implant* – (K061971)
2. Z-Systems AG – *Z-Look3 Dental Implant System* – (K062542)

Intended Use

CeraRoot dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. The CeraRoot dental implants can be used for single or multiple unit restorations in splinted or non-splinted applications. CeraRoot implants can be placed in immediate or delayed tooth extractions. CeraRoot implants are not intended for immediate loading. The CeraRoot dental implants are specially indicated in patients with metal allergies and chronic illness due to metal allergies.

Device Description

CeraRoot is an endosseous zirconia implant that incorporates both the implant and abutment into a one-piece design, and is intended for use in prosthetic dentistry to support single or multiple tooth restorations.

The main characteristics of the CeraRoot implant are its extreme hardness, and ability to be fabricated into final net shapes with very tight tolerances via state-of-the-art CNC processing. The implants are single use devices and are delivered in sterile condition having been sterilized using ethylene oxide (EtO).

Depending on the particular tooth to be replaced, CeraRoot implants are made available in five different implant shapes:

- Wide Upper Central Incisor & Cuspid,
- Upper Central Incisor & Cuspid,
- Upper Lateral & Lower Incisor,
- Bicuspid,
- Molar;

four different implant lengths:

- 8, 10, 12 & 14 mm;

and five different implant diameters:

- 3.5, 4.1, 4.8, 6, & 6.5 mm.

The CeraRoot implants have similar indications to the predicate devices produced by Z-Systems and Nobel Biocare, are made of virtually identical materials (i.e., zirconia that is at least 95% by weight ZrO_2) and are available in similar lengths and diameters. The primary difference in the CeraRoot implants and the predicate devices lies in their overall shapes, surface finish and threaded areas.

The CeraRoot implants are made available in five different unique shapes that have been designed for specific areas of the mouth, and use a *color coding* method that matches the correct implant shape to the location in the mouth where it is to be placed. The CeraRoot implants are also subjected to an acid etching process called *ICE®-surface* that is used to impart the unique surface finish to the device that helps to enhance the osseointegration process. This compares to the more conventional mechanical processes that are imparted to the surfaces of the predicate devices.

Additionally, the CeraRoot 14 Bicuspid implant is designed to be press-fit into place, as only the coronal half of the endosseous implant contains threads. The

surgical method by which this implant is placed requires that it be tapped into place, with no rotational aspect to the insertion as compared to all the remaining implant shapes, which are surgically inserted by conventional means (i.e., screwed into place). This design is unique to the CeraRoot 14 Bicuspid implant only, and is not found on any of the other predicate implants.

Non-Clinical Data – Bench Testing

As part of demonstrating safety and effectiveness of CeraRoot dental implants and in showing substantial equivalence to the predicate devices that are the subject of this 510(k) submission, Oral Iceberg submitted a selected number of its dental implants for fatigue testing in accordance with ISO 14801, *Dentistry – Implants – Dynamic Fatigue Test for Endosseous Dental Implants*, where their implants were tested in both dry (i.e., air) and wet (i.e., saline solution) environments. Testing was performed on the CeraRoot Model 14 Bicuspid implant to simulate *worst-case* loading conditions.

Further, CeraRoot dental implants also underwent extensive SEM surface analysis and surface topography studies to prove that both the acid etching and post-etching surface cleaning process used during the manufacture of these devices produced implants that resulted in a clean, textured, pure zirconia surface. Both the acid etching and surface cleaning processes were subjected to extensive validation studies to prove their repeatability.

CeraRoot dental implants also underwent biocompatibility testing in accordance with the applicable parts of ISO 10993-1, *Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing* as required for long-term dental implant devices.

Clinical Data – CeraRoot 14 Bicuspid Implant

As part of demonstrating the safety and effectiveness of CeraRoot dental implants, particularly for the CeraRoot 14 Bicuspid implant, Oral Iceberg submitted a summary report and radiographic images that were part of its European clinical study, and represent the five-year follow-up study for their implants, which have been published in the International Journal of Oral & Maxillofacial Implants [2010; 25:336-344] by Xavi Oliva, DDS, MSc, Josep Oliva, DDS, MSc & Josep D. Oliva, DDM: *Five-Tear Success Rate of 831 Consecutively Placed Zirconia Dental Implants in Humans – A Comparison of Three Different Rough Surfaces*, and in the European Journal of Esthetic Dentistry [Volume 5, Number 2 (2010) pp. 190-204] by Xavi Oliva, DDS, MSc & Josep Oliva, DDS, MSc: *Full-Mouth Oral Rehabilitation in a Titanium Allergy Patient Using Zirconium Oxide Dental Implants and Zirconium Oxide Restorations. A Case Report from an Ongoing Clinical Study.*

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 substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the CeraRoot Implant System and the predicate devices do not raise any questions regarding its safety and effectiveness. The CeraRoot Implant System, as designed and manufactured, 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-G609
Silver Spring, MD 20993-0002

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Re: K093595
Trade/Device Name: CeraRoot Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 14, 2010
Received: December 15, 2010

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. 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 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

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K093595

Device Name

CeraRoot Implant System

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Indications for Use

CeraRoot dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. The CeraRoot dental implants can be used for single or multiple unit restorations in splinted or non-splinted applications. CeraRoot implants can be placed in immediate or delayed tooth extractions. CeraRoot implants are not intended for immediate loading. The CeraRoot dental implants are specially indicated in patients with metal allergies and chronic illness due to metal allergies.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number: K093595