K093321

510(k) Summary
21 CFR 807.92

APR - 2 2010

Submitter's Name & Address

Manufacturer: BioHorizons Implant Systems, Inc.
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Birmingham, AL 35244
Phone (205) 967-7880
Fax (205) 870-0304
Official contact: Michael Davis, Regulatory Affairs Specialist
Date prepared: March 31, 2010

Name of the Device

Trade Name: BioHorizons Laser-Lok 3.0 Implant System
Common or Usual Name: Screw-type dental implant
Classification Name: Endosseous dental implant
Classification Number: Class II (21 CFR 872.3640)

Predicate Devices

1. Astra Tech AB OsseoSpeed™ Narrow, documented under 510(k) number K080396, concurrence date of April 30, 2008.
2. BioHorizons Internal Implant System, documented under 510(k) number K073268, concurrence date of February 8, 2008.
3. BioHorizons One-piece 3.0 Implant System, documented under 510(k) number K052419, concurrence date of September 20, 2005.
4. BioHorizons Tapered Internal Implant System, documented under 510(k) number K071638, concurrence date of October 10, 2007.

Device Description

BioHorizons Laser-Lok 3.0 Implants are machined titanium, screw-form endosseous dental implants supplied in 3.0mm diameter across lengths of 10.5mm, 12mm and 15mm. Implant material is titanium alloy as specified in ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications.*

The devices are further processed by roughening the threaded surface with Resorbable Blast Texture (RBT) media (tricalcium phosphate) and by application of patterns of micro-machined grooves or channels, known as Laser-Lok®, to the implant collar. The product is packaged using materials known in the industry to be appropriate for medical device packaging and is provided with a minimum sterility assurance level of 10^{-6}, validated in compliance with ANSI/AAMI/ISO 11137-1 *Sterilization of healthcare products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.*

The BioHorizons Laser-Lok 3.0 Implant System includes a series of implant abutments, as well as the usual and customary restorative components.

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Intended Use

BioHorizons Laser-Lok 3.0 Implants may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.

The implants may be restored immediately

1) with a temporary prosthesis that is not in functional occlusion,
2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or
3) for denture stabilization using multiple implants in the anterior mandible and maxilla.

The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.

Technological Characteristics

The fundamental scientific technology of the BioHorizons Laser-Lok 3.0 Implant System of endosseous dental implant devices subject to this 510(k) is substantially equivalent to the referenced predicate devices. The indication for use for conditional immediate restoration is substantially equivalent to the predicate BioHorizons Internal Implant System (K073268), and immediate restoration is an accepted and prevalent clinical practice of demonstrated safety and efficacy. The threaded portion of the implants is RBT-blasted, and Laser-Lok is applied to the implant collar.

Laser-Lok is a surface feature in which patterns of micro-machined grooves are applied to the collar of a dental implant, providing a roughened surface to establish a physical, connective tissue attachment (unlike Sharpey fiber attachment). This tissue connection:

1) is functionally oriented,
2) inhibits epithelial cell downgrowth and
3) enables crestal bone adjacent to the implant to attach and be retained.

All materials, suppliers, processing, packaging and sterilization methods remain the same as for the predicate BioHorizons Internal Implant System (K073268), and the Laser-Lok feature is substantially equivalent to that cleared for the BioHorizons Internal Implant System. The BioHorizons Laser-Lok 3.0 Implant System, which is the subject of this 510(k), is substantially equivalent to the features of the predicate implant devices which could affect safety or effectiveness because of the similarities in design, materials and intended use.

Summary of Testing

Among the information and data presented in this 510(k) submission to support the substantial equivalence of the BioHorizons Laser-Lok 3.0 Implant System to the specified predicate devices, fatigue testing demonstrated that there is substantial equivalence in the performance, safety and effectiveness between the BioHorizons Laser-Lok 3.0 Implant System and the referenced predicate devices. Fatigue testing also demonstrated that the BioHorizons Laser-Lok 3.0 Implant System meets its pre-defined acceptance criteria and performs in accordance with its intended use.

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

APR - 2 2010

Mr. Michael Davis
Regulatory Affairs Specialist
BioHorizons Implant Systems, Incorporated
2300 Riverchase Center
Birmingham, Alabama 35244

Re: K093321
Trade/Device Name: BioHorizons Laser-Lok 3.0 Implant System
Regulation Number: 21CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 31, 2010
Received: April 1, 2010

Dear Mr. Davis:

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: K093321

Device Name: BioHorizons Laser-Lok 3.0 Implant System

Indications for Use:

BioHorizons Laser-Lok 3.0 Implants may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.

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1) with a temporary prosthesis that is not in functional occlusion,
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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)

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

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