K073268

# 510(k) Summary
# 21 CFR 807.92

## Submitter's Name & Address

Manufacturer: BioHorizons Implant Systems, Inc.
2300 Riverchase Center
Birmingham, AL 35244
Phone (205) 967-7880
Fax (205) 870-0304
Official contact: Winston Greer, Vice-President, QA & RA

FEB - 8 2008

Date prepared: November 19, 2007

## Name of the Device

Trade Name: BioHorizons Internal 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. BioHorizons Internal Implant System (formerly "The Prodigy System Dental Implants"), documented under 510(k) number K042429, concurrence date of September 16, 2004.
2. BioHorizons Tapered Internal Implant System, documented under 510(k) number K071638, concurrence date of October 10, 2007.

## Device Description

BioHorizons Internal Implants are machined titanium, screw-form endosseous dental implants supplied in 3.5mm, 4.0mm, 5.0mm, 6.0mm diameters across lengths of 9mm, 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 surface with tricalcium phosphate blast media, or by applying hydroxylapatite coating conforming to ASTM F1185 *Standard Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants*, to promote implant fixation. 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 to 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 Internal Implant System includes a series of implant catalog item numbers with Laser-Lok® technology applied to the implant collar to provide additional treatment options for the dental implant clinician.

**Intended Use**

BioHorizons Internal Implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention.

BioHorizons Internal Implants may be restored immediately
1) with a temporary prosthesis that is not in functional occlusion, or
2) when splinted together for multiple tooth replacement, or when stabilized with an overdenture supported by multiple implants.

**Technological Characteristics**

The fundamental scientific technology of the BioHorizons Internal Implant System of endosseous dental implant devices subject to this 510(k) is substantially equivalent to the referenced predicate devices. The addition to the indications for use for conditional immediate restoration is substantially equivalent to the predicate BioHorizons Tapered Internal Implant System (K071638), and immediate restoration is an accepted and prevalent clinical practice of demonstrated safety and efficacy. Laser-Lok is a surface feature in which patterns of micro-machined grooves are applied to the collar surface of a dental implant to (1) inhibit epithelial cell downgrowth around the implant, and (2) attach and retain crestal bone adjacent to the implant. All materials, suppliers, processing, packaging and sterilization methods remain the same as for the predicate BioHorizons Prodigy (K042429) and Tapered Internal endosseous implants, and the Laser-Lok feature is substantially equivalent as that cleared for the Tapered Internal Implant System. The BioHorizons Internal Implant System which is the subject of this 510(k) is substantially equivalent to all features of the predicate BioHorizons Prodigy and Tapered Internal implant devices which could affect safety or effectiveness because of the similarities in design, materials and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

Dr. Winston Greer
Vice President, Quality Assurance & Regulatory Affairs
BioHorizons Implant Systems, Incorporated
2300 Riverchase Center
Birmingham, Alabama 35244

Re: K073268
Trade/Device Name: BioHorizons Internal Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 19, 2007
Received: November 20, 2007

Dear Dr. Greer:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: _____

Device Name: BioHorizons Internal Implant System

Indications for Use:

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1) with a temporary prosthesis that is not in functional occlusion, or
2) when splinted together for multiple tooth replacement, or when stabilized with an overdenture supported by multiple implants.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K073268

Prescription Use ___X___ OR Over-the-Counter Use _____
(per 21 CFR 801.109)