K053152

DEC 2 2005

**510(k) Summary**
**21 CFR 807.92**

## Submitter's Name & Address

Manufacturer: BioHorizons Implant Systems, Inc.
One Perimeter Park South
Suite 230 South
Birmingham, AL 35243
Phone: (205) 967-7880
Fax: (205) 870-0304
Official contact: Winston Greer, Vice-President, QA & RA
Date prepared: October 25, 2005

## Name of the Device

Trade Name: BioHorizons Single-stage Implant
Common or Usual Name: Screw-type Dental Implant
Classification Name: Endosseous implants, surgical components, and prosthetic attachments
Classification Number: Class II

## Predicate Devices

1. The Maestro System extended collar implants, documented under 510(k) number K020645, concurrence date of March 15, 2002.
2. The Prodigy System internal-connection implants, documented under 510(k) number K042429, concurrence date of September 16, 2005.

## Device Description

The BioHorizons Single-stage dental implants are machined titanium, screw-form implants supplied in 3.5mm, 4mm, 5mm, 6mm diameters across lengths of 7mm, 9mm, 10.5mm, 12mm and 15mm. Implant raw material is titanium alloy as specified in ASTM F 136, *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 F 1185, *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, *Sterilization of healthcare products - Requirements for validation and routine control - Radiation Sterilization.*

## Intended Use

The intended use of BioHorizons Single-stage endosseous implants is in the mandible and maxilla as an artificial root structure for single tooth replacement or as abutments for fixed bridgework and denture retention.

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## Technological Characteristics

The fundamental scientific technology of the device is identical to the referenced predicate devices. All materials, suppliers, processing, packaging and sterilization methods remain the same as for the predicate BioHorizons Single-stage endosseous implants. The BioHorizons Single-stage implants are substantially equivalent to all features of the predicate Maestro System and Prodigy System device which could affect safety or effectiveness because of the similarities in design, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2005

Mr. Winston Greer
Vice President, Quality Assurance & Regulatory Affairs
Biohorizons Implants Systems, Incorporated
One Perimeter Park South Suite 230, South
Birmingham, Alabama 35243

Re: K053152
Trade/Device Name: BioHorizons Single-Stage Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: November 8, 2005
Received: November 10, 2005

Dear Mr. 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

510(k) Number: K053152

Device Name: BioHorizons Single-stage Implant

Indications for Use:

The BioHorizons Single-stage implant may be used in the mandible and maxilla for use as an artificial root structure for single tooth replacement or as abutments for fixed bridgework and denture retention.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Susan Runner

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

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