K052419

510(k) Summary
21 CFR 807.92

Date: August 26, 2005
Official Contact: Winston Greer, Vice-President, QA & RA
Manufacturer: BioHorizons Implant Systems, Inc.
One Perimeter Park South
Suite 230 South
Birmingham, AL 35243
Phone: (205) 967-7880
Fax: (205) 870-0304

Proprietary Name

The Maximus™ 3.0mm and OS Implants

Common Name

Screw-type Dental Implant

Classification Name

Endosseous implants, surgical components, and prosthetic attachments

Predicate Devices

Predicate devices are:

1. The BioHorizons Dental Implant System, a screw-type endosseous implant manufactured and distributed by BioHorizons Implant Systems, Inc. Authorization to legally market the predicate implant device has been documented under 510(k) number K960026, concurrence date March 28, 1996.
2. BioHorizons the Maestro System™ 3.0mm diameter implant, a screw-type endosseous implant manufactured and distributed by BioHorizons Implant Systems, Inc. Authorization to legally market the predicate implant device has been documented under 510(k) number K032351, concurrence date October 21, 2003.
3. BioHorizons Maximus OS (Overdenture System) Implant, a screw-type endosseous implant manufactured and distributed by BioHorizons Implant Systems, Inc. Authorization to legally market the predicate implant device has been documented under 510(k) number K041938, concurrence date July 22, 2004.

Device Description

The BioHorizons Maximus 3.0mm and OS implants are machined titanium, screw-form implants supplied in lengths of 12mm, 15mm and 18mm and the Maximus OS implant is further supplied with tissue collar heights of 2mm and 4mm, available with each length. 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 device is further processed by treating the surface with Hydroxylapatite (HA) media 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.*

The Maximus 3.0mm and OS implants are comprehensive systems containing implants and surgical components. The Maximus 3.0mm diameter implant may be used (1) as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors, with or without tissue reflection; (2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors; and, (3) for denture stabilization using multiple implants in the anterior mandible and maxilla. In single cases they may be placed in immediate function out of occlusion with a temporary prosthesis. The Maximus OS implant is a system with the implants configured specifically for use in denture stabilization; reference the Intended Use section following.

All BioHorizons implants referenced in this submission are 3.0mm in diameter with surface treatment using Hydroxylapatite coating. The following table provides a summary of the proposed catalog item or reference numbers by implant length and collar height.

Length (mm)	**Catalog REF Number**	
	Maximus 3.0mm implant	**Maximus OS implant**
12	3012D4	3012OS2H
		3012OS4H
15	3015D4	3015OS2H
		3015OS4H
18	3018D4	3018OS2H
		3018OS4H

Intended Use

The BioHorizons Maximus 3.0mm implant may be used:

(1) as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implant may be immediately restored 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. The implants may be restored after a period of time or placed in immediate function.

(3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be restored after a period of time or placed in immediate function.

The BioHorizons Maximus OS implant may be used for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be restored after a period of time or placed in immediate function.

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 Maximus 3.0mm and OS implants. The HA-coating BioHorizons Maximus 3.0 and OS implants are substantially equivalent to all features of the predicate devices 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

SEP 2 0 2005

Mr. Winston Greer
Vice-President, QA & RA
BioHorizons Implant Systems, Incorporated
One Perimeter Park South, Suite 230
Birmingham, Alabama 35243

Re: K052419
Trade/Device Name: BioHorizons Maximus 3.0mm and OS Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 26, 2005
Received: September 2, 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.

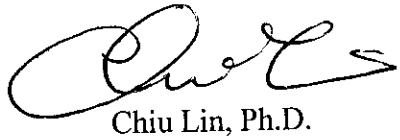
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Enclosure

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510(k) Number: K052419

Device Name: BioHorizons Maximus 3.0mm and OS Implants

Indications for Use:

The BioHorizons Maximus 3.0 Implants may be used (1) as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implant may be immediately restored 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. The implants may be restored after a period of time or placed in immediate function; (3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be restored after a period of time or placed in immediate function.

The BioHorizons Maximus OS Implants may be used for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be restored after a period of time or placed in immediate function.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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