SEP 1 6 2004

K042429

510(k) Summary
21 CFR 807.92

Date: September 3, 2004
Official Contact: Winston Greer, Director, 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 Prodigy System™ Dental Implants

Common Name

Screw-type Dental Implant

Classification Name

Endosseous implants, surgical components, and prosthetic attachments

Predicate Devices

Predicate devices are BioHorizons The Maestro™ System dental implants, 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) numbers K960026, concurrence date March 28, 1996; K010458, February 15, 2001; K020133, January 15, 2002; and K030463, February 10, 2003.

Device Description

The Prodigy System dental implants are machined titanium, screw-form implants supplied in 3.5mm, 4mm, 5mm, 6mm diameters across lengths of 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.*

The Prodigy System is a comprehensive system consisting of dental implants and surgical components. The following table provides a summary of the proposed catalog item or reference numbers by surface treatment (RBT - Resorbable Blast Texturing with tricalcium phosphate media, or HA - hydroxylapatite coating), implant diameter, and length.

Catalog REF Number	Surface	Diameter (mm)	Length (mm)
PYH3509	HA	3.5	9
PYH35105			10.5
PYH3512			12
PYH3515			15
PGH4009		4	9
PGH40105			10.5
PGH4012			12
PGH4015			15
PBH5009		5	9
PBH50105			10.5
PBH5012			12
PBH5015			15
PBH6009		6	9
PBH60105			10.5
PBH6012			12
PBH6015			15

Catalog REF Number	Surface	Diameter (mm)	Length (mm)
PYR3509	RBT	3.5	9
PYR35105			10.5
PYR3512			12
PYR3515			15
PGR4009		4	9
PGR40105			10.5
PGR4012			12
PGR4015			15
PBR5009		5	9
PBR50105			10.5
PBR5012			12
PBR5015			15
PBR6009		6	9
PBR60105			10.5
PBR6012			12
PBR6015			15

Intended Use

The intended use of The Prodigy System 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.

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 Maestro System endosseous implants. The BioHorizonsProdigy System implants are substantially equivalent to all features of the predicate Maestro 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

SEP 16 2004

Mr. Winston D. Greer
Director, Quality Assurance & Regulatory Affairs
Biohorizons Implant Systems, Incorporated
One Perimeter Park South, Suite 230 South
Birmingham, Alabama 35243

Re: K042429
Trade/Device Name: BioHorizons The Prodigy System™ Endosseous Implants
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: September 3, 2004
Received: September 8, 2004

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.

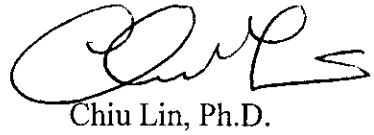
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.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: K042429

Device Name: BioHorizons The Prodigy System™ Endosseous Implants

Indications for Use:

The Prodigy System endosseous implants 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 dental retention.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K042429

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