K071638

510(k) Summary

OCT 10 2007

BioHorizons Implant Systems, Inc.
BioHorizons Tapered Internal Implant System

ADMINISTRATIVE INFORMATION

Manufacturer Name:	BioHorizons Implant Systems, Inc. One Perimeter Park South, Suite 230 South Birmingham, AL 35243 USA Telephone 1 (205) 967-7880 Fax 1 (205) 870-0304
Official Contact:	Winston Greer
Representative/Consultant:	Linda Schulz or Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone 1 (858) 792-1235 Fax 1 (858) 792-1236 email: lschulz@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	BioHorizons Tapered Internal Implant System
Common Name:	Dental implants and abutments
Classification Regulations:	Endosseous dental implant (21 CFR 872.3640), Class II Endosseous dental implant abutment (21 CFR 872.3630), Class II
Product Codes	DZE, NHA

DEVICE CLASSIFICATION PANEL

The Classification Panel for these devices is the Dental Products Panel, and they are reviewed by the Dental Devices Branch.

INTENDED USE

The BioHorizons Tapered Internal Implant System is intended for use in the mandible or maxilla for use as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention.

The BioHorizons Tapered Internal Implant System 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.

DEVICE DESCRIPTION

BioHorizons Tapered Internal Implant System is a system of tapered, threaded, internal connection, root form implants and matching abutments intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The external design of the implant is the same as that of the Bio-Lok Implant System, including the Laser-Lok® collar. The internal connection and the platform are the same as those of the BioHorizons Prodigy System™ Endosseous Implants.

EQUIVALENCE TO MARKETED PRODUCT

BioHorizons Implants Systems, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the BioHorizons Tapered Internal Implant System is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2007

BioHorizons Implant Systems, Incorporated
C/O Ms. Linda K. Schulz
Regulatory Affairs
PaxMed International, LLC
11234 EL Camino Real, Suite 200
San Diego, California 92130

Re: K071638
Trade/Device Name: BioHorizons Tapered Internal Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 26, 2007
Received: September 27, 2007

Dear Ms. Schulz:

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.

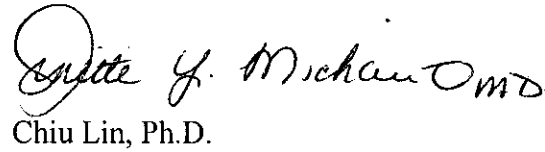
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K071638

Device Name: BioHorizons Tapered Internal Implant System

Indications for Use:

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

Susan Runner

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

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