510(k) summary
21 CFR 807.92

Date: September 22, 2006

Sponsor: BioHorizons Implant Systems, Inc.
One Perimeter Park South
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Birmingham, AL 35243
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Official Contact: Winston Greer, Vice-President, QA & RA

Proprietary Name

Biohorizons Ceramic Abutment.

Common Name

Endosseous dental implant abutment.

Classification Name

Abutment, implant, dental, endosseous (21 CFR 872.3630, Product Code NHA).

Predicate Devices

Predicate devices are the Astra Tech Ceramic Abutment (K023631) and BioHorizons The Prodigy System Endosseous Implants (K042429). The cited Astra Tech device is a ceramic abutment with essentially the same indications for use as intended for the BioHorizons Ceramic Abutment. The cited BioHorizons devices are screw-type dental implant systems which include mating titanium abutment components, manufactured and distributed by the applicant. Authorization to legally market the predicate implant dental systems and Astra Tech ceramic abutment have been documented under the referenced 510(k) numbers.

Device Description

The BioHorizons Ceramic Abutment is a prosthetic restorative component intended for use with BioHorizons dental implants. This 510(k) submission notification is for the purpose of obtaining authorization to offer ceramic prosthetic abutments as part of endosseous implant systems manufactured and marketed by BioHorizons. The abutments are manufactured from ceramic material to BioHorizons design specifications, similar to the predicate Astra Tech device, and will be provided with a mating abutment screw for attachment to the implant.

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In clinical practice the surgical placement and restorative procedures for the implants and abutments will not change. Ceramic abutments offer clinicians an esthetic treatment option with the more natural color tint of the ceramic when visible through gingival tissue, compared with the gray tint of titanium abutments.

Intended Use

BioHorizons Ceramic Abutments are intended for use in the anterior esthetic zone with BioHorizons Dental Implant-supported prosthetic restorations. BioHorizons endosseous dental 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. The basic indications and intended use of the BioHorizons ceramic abutment device are more restricted than described in predicate device labeling.

Technological Characteristics

The fundamental scientific technology of the ceramic abutment device is not changed from the predicate devices. All materials and processing methods remain substantially the same as the predicate devices.

Non-Clinical Testing

Laboratory testing was conducted on the "worst cast" (because of lesser wall thickness) 4.5mm Ceramic Abutment to determine device functionality and conformance to design requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Winston D. Greer
Vice-President, Quality Assurance & Regulatory Affairs
BioHorizons Implant Systems, Incorporated
One Perimeter Park South
Suite 230 South
Birmingham, Alabama 35243

NOV 2 2 2006

Re: K061567
Trade/Device Name: BioHorizons Ceramic Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 17, 2006
Received: November 20, 2006

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

INDICATIONS FOR USE

510(k) Number: K061567

Device Name: BioHorizons Ceramic Abutments

Indications for Use:

BioHorizons Ceramic Abutments are intended for use in the anterior esthetic zone with BioHorizons Dental Implant-supported prosthetic restorations.

BioHorizons endosseous dental 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 denture retention.

Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBetz DDS for Dr Susan Runner

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) K061567

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