FEB 14 2006

K053099

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 28, 2005

Name of the Device

Trade Name: BioHorizons Plastic Temporary Abutments
Common or Usual Name: Dental Implant Plastic Temporary Abutment
Classification Name: Abutment, Implant, Dental, Endosseous
Classification Number: NHA, 872.3630

Predicate Devices

1. Friadent Esthicap, marketed by Dentsply International, York, Pennsylvania 17405, documented under 510(k) number K050208, concurrence date June 14, 2005.
2. Straumann RN synOcta Temporary Meso Abutment, marketed by Straumann Manufacturing, Andover, Massachusetts 01810 , documented under 510(k) number K051717, concurrence date July 7, 2005.

Device Description

BioHorizons Plastic Temporary Abutments are medical grade machined polyetheretherketone (PEEK) material, supplied sterile using gamma radiation for use as short-term (30 days or less) restorative dental implant abutments.

Intended Use

BioHorizons Plastic Temporary Abutments are intended for short-term use of 30 days or less as a base for cemented or screw-retained crown and bridge restoration of dental implants, while esthetically contouring soft tissue.

Technological Characteristics

The fundamental scientific technology for the material, processing, and intended use of BioHorizons Plastic Temporary Abutments is essentially identical to the referenced predicate devices, making the BioHorizons Plastic Temporary Abutments 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

FEB 14 2006

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

Re: K053099
Trade/Device Name: BioHorizons Plastic Temporary Abutment
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 24, 2006
Received: January 26, 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.

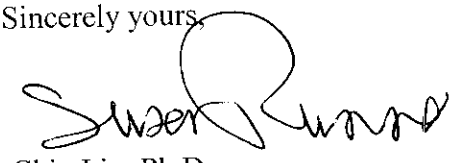
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



for 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: K053099

Device Name: BioHorizons Plastic Temporary Abutment

Indications for Use:

BioHorizons Plastic Temporary Abutments are intended for short-term use of 30 days or less as a base for cemented or screw-retained crown and bridge restoration of dental implants, while esthetically contouring soft tissue.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K053099

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