

4/9/99

1K990277

BioHorizons Implant Systems, Inc.
510(k) Notification
01/21/99

510(k) Summary of Safety and Effectiveness

Proprietary Name

O-Ring Abutment

Common Name

Overdenture Abutment

Classification Name

Accessory to Endosseous Implants and Associated Components and Instrumentation

Classification

Class III

Official Contact

Winston Greer, VP of Operations
BioHorizons Implant Systems, Inc.
One Perimeter Park South
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Device Description

The O-ring Abutment System is either a one-piece or a two-piece restorative prosthesis that provides a direct attachment for tissue-supported overdentures retained by two or more implants with up to a 10-degree divergence.

Product Evaluation

The O-Ring Abutment System has been evaluated in laboratory conditions and by consulting implantologists and oral and maxillofacial surgeons and has been found to provide a direct attachment for tissue-supported overdentures retained by two or more implants with up to a 10-degree divergence, as noted in the intended use statement.

These evaluations indicate that the O-Ring Abutment System should be safe and effective when used as intended.

Indications for Use

The BioHorizons O-Ring Abutment System is intended to provide a direct attachment for tissue-supported overdentures retained by two or more implants with up to a 10-degree divergence.

Substantial Equivalence Information

The BioHorizons O-Ring Abutment System is substantially equivalent in all features that could affect the safety and effectiveness to the Lifecore Biomedical, SteriOss, and Implant Innovations, O-Ring Abutment Systems.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 9 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Diana M. Easton
BioHorizons Implants Systems, Incorporated
One Perimeter Park South
Suite 230 South
Birmingham, Alabama 35243

Re: K990277
Trade Name: O-Ring Abutment
Regulatory Class: III
Product Code: DZE
Dated: January 21, 1999
Received: January 28, 1999

Dear Ms. Easton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Easton

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: BioHorizons O-Ring Abutment System

Indications for Use:

The BioHorizons O-Ring Abutment System is intended to provide a direct attachment for tissue-supported overdentures retained by two or more implants with up to a 10-degree divergence.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyan
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K996277

Prescription Use _____
(per 21 CFR 801.109)

OR

Over-the-Counter Use _____