K022795

510(k) summary
21 CFR 807.92

AUG 3 0 2002

Date: 08/21/2002

Official Contact: Winston Greer

Manufacturer: BioHorizons Implant Systems, Inc.
One Perimeter Park South
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Proprietary Name

The Maestro System™

Common Name

Screw-type Dental Implant

Classification Name

Endosseous implants, surgical components, and prosthetic attachments

Predicate Device

The predicate device is The Maestro System™ , a screw-type dental implant system manufactured and distributed by BioHorizons Implant Systems, Inc. Authorization to legally market the predicate BioHorizons Maestro System has been documented under 510(k) numbers K010458, K960026, K964330, K972313, K010458, K020133, K020645.

The GingiHue™ abutment from Implant Innovations Inc. (3i), is a competitive abutment utilizing a titanium nitride (Ti-N) coating. Authorization to legally market the predicate 3i abutment and implant system has been documented under 510(k) number K992334.

Device Description

The Maestro System is a comprehensive system containing implants, surgical components, and prosthetic components. This 510(k) submission notification is for the purpose of obtaining authorization to offer Ti-N coated prosthetic abutments as part of The Maestro System. The abutments will continue to be machined from titanium alloy but will undergo a Ti-N coating process. BioHorizons proposes to coat all exposed surfaces of the implant abutments during the coating process; current dimensional characteristics and specifications for abutments coated with Ti-N do not change. Cleaning, packaging and sterilization operations will be the same for the Ti-N coated abutments as for the non-coated abutments. In clinical practice, the implant and abutments surgical placement and restorative procedures will not change.

Device Description (cont'd)

The purpose of Ti-N coating implant abutments is two-fold: first, the yellow color of the Ti-N coating presents an esthetically-pleasing tint when visible through tissue, compared with the gray tint of uncoated titanium; second, the yellow color provides a distinct demarcation line at the interface of the implant body and the abutment, which will provide a visual aide in determining implant depth during the placement process.

The product is packaged using materials known in the industry to be appropriate for medical device packaging and will be provided sterile, validated in compliance to ANSI/AAMI/ISO 11137, Sterilization of healthcare products - Requirements for validation and routine control - Radiation Sterilization, with a minimum sterility assurance level of 10^{-6}.

Intended Use

The indications for use of the Ti-N coated implants and abutments do not change from non-coated implants and abutments. The Maestro System 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 indication/intended use of the modified device as described in its previously-cleared labeling has not changed.

Technological Characteristics

The fundamental scientific technology of the modified device has not changed: all materials, suppliers, processing, packaging and sterilization methods remain the same with the exception of the additional Ti-N coating process. Ti-N coating has been cleared by FDA for use in a variety of implant medical device applications since first reviewed in the 1980s. Biocompatibility testing has been conducted on Ti-N using the International Organization for Standardization (ISO 10993-1) guidelines. This testing, and subsequent clinical applications, has demonstrated that titanium nitride is biocompatible and appropriate for human use in implant medical devices that come in contact with bone, skin, tissue, or blood. The proposed Ti-N modification to The Maestro System abutment components is substantially equivalent to all features of the predicate devices which may affect safety or effectiveness, because of the similarities in design, material, and intended use.

Non-Clinical Testing

Ti-N coating applied to The Maestro System abutments was assessed in a number of tests, including adhesion and coating thickness to IonBond specification MS 70-722, and elemental composition using Energy Dispersive Spectroscopy in a scanning electron microscope at the University of Alabama at Birmingham School of Dentistry.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2002

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

Re: K022795
Trade/Device Name: The Maestro System™
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: NHA
Dated: August 21, 2002
Received: August 23, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613 . 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
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 (if known): K022795

Device Name: The Maestro System™

Indications for Use:

The Maestro System™ may be used in the mandible or maxilla for use as an artificial root structure for single tooth replacement or as abutments for fixed bridgework and denture retention.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Betz DDS for Dr Susan Runner

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

510(k) Number: K022795

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