SEP 16 1997

K972313

510(k) Summary of Safety and Effectiveness

Proprietary Name

The Maestro System™

Common Name

Uncoated and titanium plasma spray coated screw-form implants

Classification Name

Endosseous implants, surgical components, and prosthetic attachments

Classification

Class III

Official Contact

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Device Description

The Maestro System™ is a comprehensive system containing implants, surgical components, and prosthetic components. The implants are specifically designed to optimize strain distribution to contiguous bone under functional loading in order to promote strain-induced bone growth and interface maintenance over the long-term. This bone growth and interface maintenance over the long-term. This improvement in biomechanical performance is achieved by optimizing implant designs specifically for each bone density classification (D1, D2, D3, and D4) and bone volume classification (Division A, B, and C-h) in the mandible and maxilla.

Four implant designs, corresponding to each bone density and bone volume classification, are available in 3.5, 4.0,and 5.0 mm diameters. Each implant design, manufactured from titanium alloy conforming to ASTM F 136, is available in several lengths and may feature a titanium plasma-spray (TPS) or hydroxyapatite (HA) coating. The following table provides a comprehensive summary of implant diameter, length, and coating.

Diameter (mm)	Design	Lengths (mm)	Coating
ϕ3.5	D2	9, 12, 14	Uncoated
	D3	9, 13, 15	TPS
ϕ4.0	D1	10, 12	Uncoated
	D2	9, 11, 13	Uncoated
	D3	9, 12, 14	TPS
	D4	9, 13, 15	HA
ϕ5.0	D1	9, 11	Uncoated
	D2	9, 10, 12	Uncoated
	D3	9, 11, 13	TPS
	D4	9, 12, 14	HA

Table. Summary of Implant Diameter, Length, and Coating.

Product Evaluation

Evaluation of The Maestro System™ consisted of mechanical testing of the implant and bioactive coating mechanical tests. These analyses indicate The Maestro System™ should be safe and effective when used as intended.

Indications

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 denture retention.

Substantial Equivalence Information

The Maestro System™ is substantially equivalent in all features which could affect safety or effectiveness to the BioHorizons Dental Implant System (K964330) and the Steri-Oss® Hex-Lock (HL) Threaded Titanium Implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1997

Mr. R. Steven Boggan
President and Chief Operating Officer
BioHorizons Implant Systems, Incorporated
2129 Montgomery Highway
Birmingham, Alabama 35209

Re: K972313
Trade Name: The Maestro System™
Regulatory Class: III
Product Code: DZE
Dated: June 18, 1997
Received: June 20, 1997

Dear Mr. Boggan:

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 (Premarket 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 premarket 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.

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) 594-4618. 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: K972313

Device Name: BioHorizons Maestro System™

Indications for Use:

The BioHorizons Maestro System™ is indicated for use as an artificial root structure for single tooth replacement or as abutments for bridgework and denture retention in the mandible and maxilla.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K972313

Prescription Use ✓ OR Over-The-Counter Use ____
(per 21 CFR 801.109)