DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 8,2015

BioHorizons Implant Systems, Inc.
Michael Davis
Regulatory Affairs Manager
2300 Riverchase Center
Birmingham, AL 35244

Re: K143022
Trade/Device Name: BioHorizons Tapered Internal Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 9, 2014
Received: December 10, 2014

Dear Mr. Davis:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K143022

Device Name: BioHorizons Tapered Internal Implants

Indications for Use:

BioHorizons Tapered Internal Implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The implants may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion or (2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K143022

SlO(k) Summary
21 CFR 807.92

Submitter's Name & Address

Manufacturer: BioHorizons Implant Systems, Inc.
2300 Riverchase Center
Birmingham, AL 35244
Phone(205)967-7880
Fax (205) 870-0304
Official contact: Michael Davis, Regulatory Affairs Manager
Date prepared: December 2, 2014

Name of the Device

Trade Name: BioHorizons Tapered Internal Implants
Common or Usual Name: Screw-type dental implant
Classification Name: Endosseous dental implant
Classification Number: Class II (21 CFR 872.3640)

Predicate Devices

1. BioHorizons Tapered Internal Implant System, documented under 510(k) number K071638, concurrence date of October 10,2007.
2. BioHorizons Laser-Lok 3.0 Implant System, documented under 510(k) number K093321, concurrence date of April 2, 2010.

Device Description

The BioHorizons Tapered Internal Implants are machined titanium, screw-form endosseous dental implants supplied in 3.4mm, 3.8mm and 4.6mm diameters. The 3.4mm diameter implant includes lengths of 9mm, 10.5mm, 12mm, 15mm and 18mm while the 3.8mm and 4.6mm diameter implants include an 18mm length option to complement currently cleared implant lengths within those implant body diameters. Implant material is titanium alloy as specified in ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications.*

The devices are further processed by roughening the threaded surface with Resorbable Blast Texture (RBT) media (tricalcium phosphate) and by micro-machining grooves, known as Laser• Lok® microchannels, to the implant collar of select models. The product is packaged using materials known in the industry to be appropriate for medical device packaging and is provided with a minimum sterility assurance level of 10^{-6}, validated in compliance with ANSVAAMI/ISO 11137-1 *Sterilization of healthcare products -- Radiation -- Part I: Requirements for development, validation and routine control of a sterilization process for medical devices.*

Intended Use

BioHorizons Tapered Internal Implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The implants may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion or (2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants.

Technological Characteristics

The fundamental scientific technology of the BioHorizons Tapered Internal endosseous dental implant devices subject to this 51O(k) is substantially equivalent to the referenced predicate devices. The threaded portion of the implants is RET-blasted, and Laser-Lok microchannels are applied to the implant collar of select models.

Laser-Lok is a surface feature in which patterns of micro-machined grooves are applied to the collar of a dental implant, providing a roughened surface to establish a physical, connective tissue attachment. This tissue connection:

1) is functionally oriented,
2) inhibits epithelial cell downgrowth and
3) enables crestal bone adjacent to the implant to attach and be retained.

All materials, suppliers, processing, packaging and sterilization methods remain the same as for the predicate BioHorizons Tapered Internal Implant System (K071638) and BioHorizons Laser• Lok 3.0 Implant System (K093321). The Laser-Lok feature is substantially equivalent to that cleared for the predicate devices. The BioHorizons Tapered Internal Implants are substantially equivalent to the features of the predicate implant devices which could affect safety or effectiveness because of the similarities in design, materials and intended use. Refer to Table 1, Summary Table of Substantial Equivalence, immediately following on the next page.

Summary of Testing

Mechanical testing of the 3.0mm implant-abutment connection (as featured in the subject devices) was performed in accordance with the Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, May 12, 2004 and ISO 14801. The load-bearing features of the implant-abutment connection were tested in conjunction with angled prosthetic abutments representative of the worst-case scenario. The results of the fatigue load testing demonstrate that the subject devices are substantially equivalent to the predicate devices.

Conclusion

The data presented in this submission demonstrates that the new devices are substantially equivalent with respect to performance, safety and effectiveness for their intended use and perform as well as the referenced predicate device.

Table 1. Summary Table of Substantial Equivalence

	Subject Device	Predicate Devices	
	BioHorizons Implant Systems, Inc. !Modified! Tapered Internal Implants	BioHorizons Implant Systems, Inc. Tapered Internal Implant System K071638	BioHorizons Implant Systems, Inc. Laser-Lok 3.0 Implant System K093321
Intended Use	Biol-lorizons Tapered Internal Implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. Biol-Iorizons Tapered Internal Implants may be restored immediately I) with a temporary prosthesis that is not in functional occlusion, or 2) when splinted together for multiple tooth replacement, or when stabilized with an overdenture supported by multiple implants.	Biol-lorizons Tapered Internal Implant System is intended for use in the mandible or maxilla for use as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. Biol-lorizons Tapered Internal Implant System may be restored immediately I) with a temporary prosthesis that is not in functional occlusion, or 2) when splinted together for multiple tooth replacement, or when stabilized with an overdenture supported by multiple implants.	Biol-lorizons Laser-Lok 3.0 Implants may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately I) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.
Design			
Implant shape	Tapered	Tapered	Parallel-wall with 2.5mm apical taper
Implant body diameter	3.4mm, 3.8mm, 4.6mm	3.8mm, 4.6mm, 5.8mm	3.0mm
Implant length	9mm, 10.5mm, 12mm, 15mm, 18mm	7.5mm (except 3.8mm body), 9mm, 10.5mm, 12mm, 15mm	10.5mm, 12mm, 15mm
Outer thread	External Buttress	External Buttress	Square
Surface	Implant- RBT Collar- Laser-Lok or RBT	Implant- RBT or HA Collar- Laser-Lok	Implant - RBT Collar- Laser-Lok
Hex connection	Internal	Internal	Internal
Internal thread	Spiralock UNF 1-72	Spiralock UNF 1-72	Spiralock UNF 1-72
Prosthetic platform	3.0mm, 3.5mm, 4.5mm	3.5mm, 4.5mm, 5.7mm	3.0mm
Material and Manufacturing			
Implant Material	Ti-6Al-4V (ASTM Fl36)	Ti-6AI-4V (ASTM Fl36)	Ti-6Al-4V (ASTM F136)
Manufacturing process	Machined by BioHorizons or A-level supplier, surface treated with micro-machined grooves (Laser-Lok) and RBT or RBTonly	Machined by BioHorizons or A-level supplier, surface treated with micro-machined grooves (Laser-Lok) and RBT or HA	Machined by BioHorizons or A-level supplier, surface treated with micro-machined grooves (Laser-Lok) and RBT
Packaging	Tyvek-lidded blister tray (primary package), placed inside a tamper-evident outer box (secondary package)	Tyvek-lidded blister tray	Tyvek-lidded blister tray
Sterilization	25-40 kGy gamma irradiation dose range	20-40 kGy gamma irradiation dose range	20-40 kGy gamma irradiation dose range