BioHorizons Implant Systems, Inc.
Michael Davis
Director, Regulatory Affairs
2300 Riverchase Center
Birmingham, Alabama 35244

November 22, 2017

Re: K172576
Trade/Device Name: BioHorizons Tapered Short Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: August 25, 2017
Received: August 28, 2017

Dear Michael 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

forTina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172576

Device Name
BioHorizons Tapered Short Implants

Indications for Use *(Describe)*
BioHorizons Tapered Short 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 using delayed loading, or with a terminal or intermediate abutment for fixed or removable bridgework, and for overdentures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K172576

510(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, Director, Regulatory Affairs

Date prepared: November 21, 2017

Name of the Device

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

Predicate Devices

Primary Predicate Device:

1. K121787, BioHorizons Tapered Internal Plus Implants, September 5, 2012.

Reference Predicate Devices:

1. K150571, Biomet 3i T3 Short Implants, November 20, 2015.
2. K073368, Bicon, LLC The Bicon 5.0 x 5.0mm and 6.0 x 5.0mm Dental Implant, October 10, 2008.
3. K050712, Bicon, LLC 4.5 x 6.0mm and 6.0 x 6.0mm Dental Implant, May 16, 2005.

Device Description

The BioHorizons Tapered Short Implants are machined titanium, screw-form endosseous dental implants supplied in 4.6mm and 5.8mm diameters. The 4.6mm diameter implant includes a 3.5mm prosthetic platform, while the 5.8mm diameter implant includes a 4.5mm prosthetic platform. The implants are provided in 6.0mm and 7.5mm lengths across both 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, on the implant collar. 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 ANSI/AAMI/ISO 11137-1 *Sterilization of healthcare products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.*

Indications for Use

BioHorizons Tapered Short 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 using delayed loading, or with a terminal or intermediate abutment for fixed or removable bridgework, and for overdentures.

The main difference between the Indications for Use statements between the subject device and the primary predicate device is with regard to immediate versus delayed loading protocols. The subject device is intended for delayed loading, whereas the primary predicate device was cleared for immediate restoration 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. Both devices are indicated for fixed or removeable bridgework and for overdentures. No other substantive differences exist between the Indications for Use statements between the subject and primary predicate devices.

Technological Characteristics

The fundamental scientific technology of the BioHorizons Tapered Short endosseous dental implant devices subject to this 510(k) is substantially equivalent to the referenced primary predicate device. The threaded portion of the implants is RBT-blasted, and Laser-Lok microchannels are applied to the implant collar.

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.

The preceding claims 1-3 are supported in the published literature by Nevins *et al.* Human Histologic Evidence of a Connective Tissue Attachment to a Dental Implant, International Journal of Periodontics & Restorative Dentistry 2008; 28:111-121.

All materials, suppliers, processing, packaging and sterilization methods remain the same as for the primary predicate device, BioHorizons Tapered Internal Plus Implants (K121787). The Laser-Lok feature is substantially equivalent to that cleared for the BioHorizons Tapered Internal Plus Implants. The BioHorizons Tapered Short Implants are substantially equivalent to the features of the predicate implant devices because of the similarities in design, materials and intended use. Refer to Table 1, Summary Table of Substantial Equivalence, immediately following.

Summary of Testing

Mechanical fatigue testing of the worst-case (smallest prosthetic platform/smallest implant body diameter combined with the shortest implant length) 4.6mm x 6.0mm Tapered Short Implant 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. Additionally, surface area and bone-to-implant contact (BIC) comparative analysis was performed in accordance with BioHorizons internally developed test protocol, followed by axial pullout testing in accordance with ASTM F543. Analysis compared the shortest length worst-case subject implants across both offered implant diameters to the shortest length worst-case primary predicate implants across equivalent implant diameters. Both evaluations demonstrated that the subject device provides increased external surface area, increased bone-to-implant contact and increased axial pullout strength as compared to the primary predicate device.

Per FDA Guidance on “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile,” BioHorizons conducted baseline

validation testing of representative worst-case BioHorizons endosseous dental implant devices using the Limulus Amebocyte Lysate (LAL) Method – Inhibition/Enhancement Assay (per USP Chapter <85>) for bacterial endotoxins. Testing demonstrated that EU/Device was less than 0.050 for all lots tested, which is below the established acceptance criteria of 20 EU/Device for medical devices not intended to contact cerebrospinal fluid.

Sterilization validation was performed in accordance with ANSI/AAMI/ISO 11137-1. Validation testing was conducted on representative worst-case BioHorizons dental implant devices and demonstrates (1) that a minimum gamma radiation sterilization dose of 25kGy is substantiated for BioHorizons dental implant products, and (2) that BioHorizons dental implant products sterilized with a minimum 25 kGy gamma radiation dose may be released based on data from dosimeters without the need for sterility testing of each log.

Shelf life testing was performed in accordance with applicable ASTM standards for evaluating seal strength of flexible barrier materials and porous medical packaging common to all BioHorizons sterile-packaged dental implants. Test results established the shelf life to be five years provided the sterile seal is not breached. The subject device is a titanium alloy, non-mechanical, non-active device, therefore, degradation in performance characteristics is not likely over the established shelf life period. Special storage conditions are not required for the device, as ambient storage conditions are not expected to adversely affect the safety or efficacy of the device.

Additional data relied on from BioHorizons previous dental implant device submissions to demonstrate substantial equivalence to the predicate devices includes evaluation of the RBT surface treatment process as is applied to all BioHorizons dental implant devices. Evaluation included Scanning Electron Microscopy (SEM) at 100X, 1000X and 5000X demonstrating effective removal of all residual HA particulates, as well as Energy Dispersive X-Ray (EDX) spectroscopy demonstrating that there is no effect on the biocompatibility of the underlying titanium alloy material from RBT processing.

Finally, BioHorizons Tapered Short Implants meet the chemical and mechanical requirements of ASTM F136. This grade of Titanium is commonly used in surgical implant applications thus no special biocompatibility testing was conducted for the proposed devices. Historical biocompatibility testing conducted on representative BioHorizons dental implant devices that used the same ASTM F136 titanium alloy material that is used exclusively in the manufacture of all BioHorizons dental implant devices included cytotoxicity, irritation and sensitization testing. Test results concluded that the test articles were non-cytotoxic, non-irritating and negative for evidence of dermal sensitization under the test conditions employed.

Conclusion

The data presented in this submission demonstrates that the proposed devices are substantially equivalent with respect to performance and intended use. The proposed devices perform as well as the legally marketed predicate devices. Furthermore, the proposed devices do not pose any new or increased risks as compared to the legally marketed predicate devices.

Table 1. Summary Table of Substantial Equivalence

	Subject Device	Primary Predicate Device	Reference Predicate Devices		
	BioHorizons Implant Systems, Inc. Tapered Short Implants K172576	**BioHorizons Implant Systems, Inc. Tapered Internal Plus Implants K121787**	**Biomet 3i 3i T3 Short Implants K150571**	**Bicon LLC The Bicon 5.0 x 5.0mm and 6.0 x 5.0mm Dental Implant K073368**	**Bicon LLC 4.5 x 6.0mm and 6.0 x 6.0mm Dental Implant K050712**
Intended Use	BioHorizons Tapered Short 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 using delayed loading, or with a terminal or intermediate abutment for fixed or removable bridgework, and for overdentures.	BioHorizons Tapered Internal Plus Implants are 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. BioHorizons Tapered Internal Plus 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.	The 3i T3® Short Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.	The 5.0 x 5.0mm and the 6.0 x 5.0mm implants are designed as a one stage or two stage surgical procedure implant for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework, partial dentures, or a single tooth replacement.	The 4.5 x 6.0mm and the 6.0 x 6.0mm implants are designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework, partial dentures, or a single tooth replacement.
Design					
Implant shape	Tapered	Tapered	Parallel wall	Parallel wall	Parallel wall
Implant body diameter	4.6mm, 5.8mm	3.8mm, 4.6mm, 5.8mm	5.0mm, 6.0mm	5.0mm, 6.0mm	4.5mm, 6.0mm
Implant length	6.0mm, 7.5mm	7.5mm (except 3.8mm body), 9mm, 10.5mm, 12mm, 15mm	5.0mm, 6.0mm	5.0mm	6.0mm
Outer thread	Buttress	Buttress	V-thread	Fin design (tapped into place, not screwed)	Fin design (tapped into place, not screwed)
Surface	Implant - RBT Collar - Laser-Lok	Implant - RBT Collar - Laser-Lok	T3 (blasted, acid etched) or T3 DCD (blasted, acid etched and calcium phosphate applied to surface)	Integra-Ti (grit blasted, acid etched) or Integra-CP (hydroxylapatite surface)	Integra-Ti (grit blasted, acid etched) or Integra-CP (hydroxylapatite surface)
Connection	Internal Hex	Internal Hex	Flat to flat butt joint	Tapered connection, non-indexing	Tapered connection, non-indexing
Internal thread	Spiralock UNF 1-72	Spiralock UNF 1-72	Not known	Not known	Not known
Prosthetic platform	3.5mm, 4.5mm	3.0mm, 3.5mm, 4.5mm	Not known	Not known	Not known
Material and Manufacturing					
Implant Material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Grade 4 pure titanium	Ti-6Al-4V	Ti-6Al-4V
Manufacturing process	Machined by BioHorizons or A-level supplier, surface treated with micro-machined grooves (Laser-Lok) and RBT	Machined by BioHorizons or A-level supplier, surface treated with micro-machined grooves (Laser-Lok) and RBT	Not known - proprietary	Not known - proprietary	Not known - proprietary
Packaging	Tyvek-lidded blister tray (primary package), placed inside a tamper-evident outer box (secondary package)	Tyvek-lidded blister tray (primary package), placed inside a tamper-evident outer box (secondary package)	Not known	Not known	Not known
Sterilization	25-40 kGy gamma irradiation dose range	25-40 kGy gamma irradiation dose range	Not known	Not known	Not known