October 10, 2018

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

Re: K182070
Trade/Device Name: BioHorizons Tapered IM Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: September 7, 2018
Received: September 11, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Andrew I. Steen -S

for Tina 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
BioHorizons Tapered IM Implants

Indications for Use *(Describe)*
BioHorizons Tapered IM 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.

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.

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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: October 10, 2018

Name of the Device

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

Predicate Devices

Primary Predicate Device:

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

Reference Predicate Devices:

1. K103691, BioHorizons Abutments for Zimmer, November 3, 2011.
2. K151621, BioHorizons CAD/CAM Abutments, January 13, 2016.
3. K071638, BioHorizons Tapered Internal Implant System, October 10, 2017.
4. K071161, Endosseous Dental Implant System, November 16, 2007.

Device Description

The BioHorizons Tapered IM Implants are machined titanium, screw-form endosseous dental implants supplied in 7.0mm and 8.0mm diameters. Both implants include a 5.7mm prosthetic platform. The implants are provided in 7.5mm, 9.0mm and 10.5mm 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 (hydroxylapatite) 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 IM 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 IM endosseous dental implant devices subject to this 510(k) is substantially equivalent to the 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 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 and Ricci *et al.* Bone Response to Laser Microtextured Surfaces, Bone Engineering 2000:382-392.

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 IM 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

A comparative dimensional assessment was performed comparing the worst-case subject Tapered IM implant device (smallest implant body diameter combined with the shortest implant length) to the worst-case predicate Tapered Internal Plus implant device and Tapered Internal implant device (smallest prosthetic platform/smallest implant body diameter combined with the shortest implant length). The intent of the assessment was to develop objective evidence that the Tapered IM implant is substantially equivalent to the Tapered Internal Plus implant and the Tapered Internal implant as it relates to design and mechanical strength. Acceptance criteria dictated that the Tapered IM implant connection geometry, in relation to the implant external profile, shall have equal or greater (≥) wall thickness compared to the Tapered Internal Plus implant and the Tapered Internal implant. In addition to the dimensional assessment, a retrospective review of mechanical testing for the predicate Tapered Internal Plus implant and Tapered Internal Implant was also performed. Dynamic mechanical fatigue testing was performed in accordance with ISO 14801, *Dentistry - Implants - Dynamic Fatigue Test for Endosseous Dental Implants* for the worst-case 3.8mm x 15mm Tapered Internal Plus implant assembled with a 3.0mm Angled Esthetic Abutment and the worst-case 3.8mm x 15mm Tapered Internal implant assembled with a 3.5mm Angled Custom Abutment. The implant-abutment assemblies survived three consecutive fatigue runouts for 5 million cycles. The predicate device fatigue testing was included in the applicable 510(k). The aforementioned comparative dimensional assessment combined with the successful fatigue testing of the worst-case predicate device qualify the Tapered Internal IM implants for their intended use.

Sterilization validation was evaluated in accordance with ANSI/AAMI/ISO 11137-1. Validation parameters were established for this device and are substantially equivalent to those used in the primary predicate device cleared under K121787.

Endotoxin testing is routinely performed in accordance with ANSI/AAMI ST72. Testing consistently demonstrates that endotoxin levels do not exceed the acceptance limit of 20.0 EU per device per USP <161>.

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. The surface and processing used in this device are substantially equivalent to those used in the reference predicate device cleared under K071638.

Finally, BioHorizons Tapered IM 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. The material and processing used in this device are substantially equivalent to those used in the reference predicate device cleared under K071638.

Conclusion

The data presented in this submission demonstrates that the proposed device is substantially equivalent to the primary predicate devices with respect to performance and intended use. Any risks associated with differences noted in the Indications for Use of the proposed device and predicate devices have been mitigated by additional information included in the Warnings and Precautions section of the Instructions for Use. The additional information includes limiting use of the proposed device to the molar region, providing placement recommendations, and adding clinician considerations for use of these devices.

The proposed device performs as well as the legally marketed predicate devices. Furthermore, the proposed device does 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 IM Implants K182070	**BioHorizons Implant Systems, Inc. Tapered Internal Plus Implants K121787**	**BioHorizons Implant Systems, Inc. Abutments for Zimmer K103691**	**BioHorizons Implant Systems, Inc. CAD/CAM Abutments K151621**	**BioHorizons Implant Systems, Inc. Tapered Internal Implant Systems K071638**	**Southern Implant – Endosseous Dental Implant System K071161**
Intended Use	BioHorizons Tapered IM 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 IM 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.	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.	BioHorizons Abutments for Zimmer® are abutments that include healing abutments for contouring tissue and final restorative abutments to support a prosthesis. The abutments may be used for a single or multiple unit restoration and are compatible for use with BioHorizons Internal and Tapered Internal implant systems and Zimmer® Dental Screw-Vent® and Tapered Screw-Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex-connection mating platform diameters. BioHorizons Titanium Base Abutments and Laser-Lok Titanium Base Abutments are intended to be used to be used as straight abutments.	BioHorizons CAD/CAM Abutments are dental abutments placed onto a dental implant to provide support for dental prosthetic restorations. The abutments include: 1) Titanium abutment blanks with a pre-machined implant connection where the upper portion may be custom-milled in accordance with a patient-specific design using CAD/CAM techniques; and 2) Titanium bases with a pre-machined implant connection upon which a CAD/CAM designed superstructure may be fitted to complete a two-piece dental abutment. The abutments include an abutment screw for fixation to the underlying implant. The abutments may be used for single-unit (single-tooth) or multiple-unit (bridges and bars) restorations and are compatible for use with BioHorizons Internal and Tapered Internal implant systems and Zimmer® Dental Screw-Vent® and Tapered Screw-Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex-connection mating platform diameters. All digitally designed abutments and/or copings for use with BioHorizons CAD/CAM Abutments are intended to be sent to a BioHorizons-validated milling center for manufacture. BioHorizons abutments designed using CAD/CAM techniques must fulfill the BioHorizons allowable range of design parameters.	BioHorizons Tapered Internal Implant Systems 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. BioHorizons Tapered Internal 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 NSI MAX Implant System is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides support for fixed or removable dental prostheses in a single tooth, partially endentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.
Design						
Implant shape	Tapered	Tapered	N/A	N/A	Tapered	Tapered

Implant body diameter	7.0mm, 8.0mm	3.8mm, 4.6mm, 5.8mm	N/A	N/A	3.8mm, 4.6mm, 5.8mm	7mm, 8mm and 9mm diameter
Implant length	7.5mm, 9.0mm, 10.5mm	7.5mm (except 3.8mm body), 9mm, 10.5mm, 12mm, 15mm	N/A	N/A	7.5mm, 9.0mm, 10.5mm, 12.0mm, 15mm	7.0mm, 9.0mm, 11.0mm
Outer thread	Buttress	Buttress	N/A	N/A	Reverse Buttress	V-thread
Surface	Implant - RBT Collar - Laser-Lok	Implant - RBT Collar - Laser-Lok	Anodize, TiN coating, Laser-Lok	Anodize, TiN coating, Laser-Lok	Implant – RBT, HA Collar – Laser-Lok or Machined	Machined collar and blasted body
Connection	Internal Hex	Internal Hex	Internal Hex	Internal Hex	Internal Hex	External hex, Tri-Nex, IT (internal connection)
Internal thread	Spiralock UNF 1-72	Spiralock UNF 1-72	N/A	N/A	Spiralock UNF 1-72	V-thread – size unknown
Prosthetic platform	5.7mm	3.0mm, 3.5mm, 4.5mm	3.5mm, 4.5mm, 5.7mm	3.0mm, 3.5mm, 4.5mm, 5.7mm	3.5mm, 4.5mm, 5.7mm	External hex: 5.0mm, 6.0mm, 7.0mm Tri-Nex: 5.0mm, 6.0mm IT (internal connection): 4.8mm, 6.5mm
Material and Manufacturing						
Implant Material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Titanium – grade unknown
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	Machined by BioHorizons or A-level supplier, select models are surface treated with micro-machined grooves (Laser-Lok), TiN coating and anodized on the hex connection	Machined by BioHorizons or A-level supplier, select models are surface treated with micro-machined grooves (Laser-Lok), TiN coating and anodized on the hex connection (except 3.0mm hex)	Machined by BioHorizons or A-level supplier, surface treated with micro-machined grooves (Laser-Lok) and RBT	Unknown
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)	Poly/Tyvek pouch	Poly/Tyvek pouch	Tyvek-lidded blister tray	Unknown
Sterilization	25-40 kGy gamma irradiation dose range	25-40 kGy gamma irradiation dose range	N/A; abutments provided non-sterile for moist heat sterilization	N/A; abutments provided non-sterile for moist heat sterilization	25-40 kGy gamma irradiation dose range	Unknown