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
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:

Reference Predicate Devices:

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


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

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>Design</th>
<th>Implant shape</th>
<th>Tapered</th>
<th>Tapered</th>
<th>N/A</th>
<th>Tapered</th>
<th>Tapered</th>
<th>Tapered</th>
</tr>
</thead>
</table>

**Intended Use**

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.

**Design**

<table>
<thead>
<tr>
<th>Implant shape</th>
<th>Tapered</th>
<th>Tapered</th>
<th>N/A</th>
<th>N/A</th>
<th>Tapered</th>
<th>Tapered</th>
<th>Tapered</th>
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</table>

**Special 510(k) Premarket Notification**

BioHorizons Tapered IM Implants – K182070
<table>
<thead>
<tr>
<th>Feature</th>
<th>7.0mm, 8.0mm</th>
<th>3.8mm, 4.6mm, 5.8mm</th>
<th>N/A</th>
<th>3.8mm, 4.6mm, 5.8mm</th>
<th>7mm, 8mm and 9mm diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant body diameter</td>
<td>7.0mm, 8.0mm</td>
<td>3.8mm, 4.6mm, 5.8mm</td>
<td>N/A</td>
<td>3.8mm, 4.6mm, 5.8mm</td>
<td>7mm, 8mm and 9mm diameter</td>
</tr>
<tr>
<td>Implant length</td>
<td>7.5mm, 9.0mm, 10.5mm</td>
<td>N/A</td>
<td>7.5mm, 9.0mm, 10.5mm, 12.0mm, 15mm</td>
<td>7.0mm, 9.0mm, 11.0mm</td>
<td></td>
</tr>
<tr>
<td>Outer thread</td>
<td>Butress</td>
<td>N/A</td>
<td>N/A</td>
<td>Reverse Butress</td>
<td>V-thread</td>
</tr>
<tr>
<td>Surface</td>
<td>Implant - RBT Collar - Laser-Lok</td>
<td>Anodize, TiN coating, Laser-Lok</td>
<td>Anodize, TiN coating, Laser-Lok</td>
<td>Implant – RBT, HA Collar – Laser-Lok or Machined</td>
<td>Machined collar and blasted body</td>
</tr>
<tr>
<td>Connection</td>
<td>Internal Hex</td>
<td>Internal Hex</td>
<td>Internal Hex</td>
<td>Internal Hex</td>
<td>External hex, Tri-Nex, IT (internal connection)</td>
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<tr>
<td>Internal thread</td>
<td>Spiralock UNF 1-72</td>
<td>Spiralock UNF 1-72</td>
<td>N/A</td>
<td>Spiralock UNF 1-72</td>
<td>V-thread – size unknown</td>
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<tr>
<td>Prosthetic platform</td>
<td>5.7mm</td>
<td>3.0mm, 3.5mm, 4.5mm</td>
<td>3.5mm, 4.5mm, 5.7mm</td>
<td>3.5mm, 4.5mm, 5.7mm</td>
<td>3.5mm, 4.5mm, 5.7mm</td>
</tr>
<tr>
<td>Material and Manufacturing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturing process</td>
<td>Machined by BioHorizons or A-level supplier, surface treated with micro-machined grooves (Laser-Lok) and RBT</td>
<td>Machined by BioHorizons or A-level supplier, surface treated with micro-machined grooves (Laser-Lok) and RBT</td>
<td>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</td>
<td>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)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Packaging</td>
<td>Tyvek-lidded blister tray (primary package), placed inside a tamper-evident outer box (secondary package)</td>
<td>Tyvek-lidded blister tray (primary package), placed inside a tamper-evident outer box (secondary package)</td>
<td>Poly/Tyvek pouch</td>
<td>Poly/Tyvek pouch</td>
<td>Tyvek-lidded blister tray</td>
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<tr>
<td>Sterilization</td>
<td>25-40 kGy gamma irradiation dose range</td>
<td>25-40 kGy gamma irradiation dose range</td>
<td>N/A; abutments provided non-sterile for moist heat sterilization</td>
<td>N/A; abutments provided non-sterile for moist heat sterilization</td>
<td>25-40 kGy gamma irradiation dose range</td>
</tr>
</tbody>
</table>