September 28, 2018

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

Re: K180998
Trade/Device Name: BioHorizons CAD/CAM Bars
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 28, 2018
Received: August 30, 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)*
K180998

Device Name
BioHorizons CAD/CAM Bars

Indications for Use *(Describe)*
BioHorizons CAD/CAM Bars are intended for use as superstructures of a multiple-unit endosseous dental implant system, attaching directly to implants or abutments, to support a prosthetic device in a partially or fully endentulous patient for the purpose of restoring chewing function. Implant-level bars are compatible with all BioHorizons Internal and Tapered Internal implant systems. Implant-level bars are compatible with Zimmer Dental Screw-Vent® and Tapered Screw Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex connection mating platform diameters and are intended to be used with straight bar cylinders only. Abutment-level bars are compatible with BioHorizons Multi-unit Abutments.

All digitally designed BioHorizons CAD/CAM Bars are intended to be sent to a BioHorizons-validated milling center for manufacture.

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.
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Birmingham, AL 35244
Phone (205) 967-7880
Fax (205) 870-0304
Official contact: Michael Davis, Director, Regulatory Affairs
Date prepared: September 28, 2018

Name of the Device

Trade Name: BioHorizons CAD/CAM Bars
Common or Usual Name: Dental implant abutment
Classification Name: Endosseous dental implant abutment
Classification Number: Class II (21 CFR 872.3630)
Primary Product Code : NHA

Predicate Devices

Primary Predicate Device: K080864, Biomet 3i CAM StructSURE® Precision Milled Bars, July 21, 2008

Device Description

The BioHorizons CAD/CAM Bars are computer aided designed (CAD), precision computer aided milled (CAM) superstructures manufactured for individual patients. The BioHorizons CAD/CAM Bars provide support for a fixed or removable prosthetic device. The BioHorizons CAD/CAM Bars will be provided in a fixed shape configuration (e.g. Dolder®, Hader, Round) or a free form shape configuration (e.g. Freeform/Milled, Hybrid, Montreal, Paris, Wrap Around), both configurations designed to fit the individual needs of the patient. The BioHorizons CAD/CAM Bars will be provided with either an implant-level or abutment-level connection interface. Implant-level CAD/CAM bars will include passive, non-indexing connection geometry with seating on the coronal (top) surface of the implant. Abutment-level CAD/CAM bars will include passive, non-indexing connection geometry with seating on the restorative platform of the abutment. The occlusal surface of the CAD/CAM bars may include connection geometry (e.g. female threads) to accept overdenture attachments. Bar 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 CAD/CAM Bars are provided non-sterile, and they are packaged using materials known in the industry to be appropriate for medical device packaging.

When used with BioHorizons Internal and Tapered Internal implant systems, the BioHorizons CAD/CAM bars allow for up to 40° divergence between bar cylinders, with no individual bar cylinder angulated greater than 20° from the vertical axis. Only straight bar cylinders are compatible with the Zimmer Dental Screw-Vent® and Tapered Screw Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex connection mating platform diameters.

Minimum and Maximum Size Ranges

Implant Level Bars			
	Description	Minimum	Maximum
A	Platform Seating Diameter	3.0mm	5.7mm
B	Total Cylinders	2	10
C	Bar Span Between Cylinders	0mm	30mm
D	Bar Height incl. Cylinder	2.5mm	11mm
E	Maximum Angulation Per Cylinder*	0°	20°
F	Cylinder Diameter	3.0mm	10.0mm
G	Distal Extension	0mm	1.5x AP** Spread

***Does not apply to third-party compatible implant lines.**
****Anterior-Posterior**

Abutment Level Bars			
	Description	Minimum	Maximum
A	Platform Seating Diameter	4.8mm	7mm
B	Total Cylinders	2	10
C	Bar Span Between Cylinders	0mm	30mm
D	Bar Height incl. Cylinder	2.5mm	11mm
E	Maximum Angulation Per Cylinder*	0°	20°
F	Cylinder Diameter	3.0mm	10.0mm
G	Distal Extension	0mm	1.5x AP** Spread

***Does not apply to third-party compatible implant lines.**
****Anterior-Posterior**

Indications for Use

BioHorizons CAD/CAM Bars are intended for use as superstructures of a multiple-unit endosseous dental implant system, attaching directly to implants or abutments, to support a prosthetic device in a partially or fully endentulous patient for the purpose of restoring chewing function. Implant-level bars are compatible with all BioHorizons Internal and Tapered Internal implant systems. Implant-level bars are compatible with Zimmer Dental Screw-Vent® and Tapered Screw Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex connection mating platform diameters and are intended to be used with straight bar cylinders only. Abutment-level bars are compatible with BioHorizons Multi-unit Abutments.

All digitally designed BioHorizons CAD/CAM Bars are intended to be sent to a BioHorizons-validated milling center for manufacture.

Comparison of Indications for Use

The primary difference in the Indications for Use statements between the subject device and the primary predicate device is with regard to the claimed compatibility with competitor implant connections (compatibility with Zimmer Dental in the case of the subject device versus no claim of competitor implant compatibility for the predicate device). BioHorizons conducts routine competitive device compatibility assessment in accordance with internal procedural requirements. Both devices are intended to support multiple tooth prostheses in the mandible or maxilla. 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 CAD/CAM Bars that are the subject of this 510(k) is substantially equivalent to the referenced primary predicate device. Both the subject device and predicate device include similar features such as bar base material, bar-implant/bar-abutment connection tailored to the endosseous dental implant(s) and multi-unit restorative

abutment component(s) with which the device is intended to be used, prosthetic platform sizes and mode of prosthetic retention which thereby demonstrates substantial equivalence in their respective designs. Any specific differences related to bar shape, prosthetic platform connection geometry, maximum implant span and wording in the indications for use between the subject device and the predicate device have been mitigated based on the performance testing conducted on the worst-case manufactured dimensions which supports the determination that the subject devices are appropriate for their intended use and do not render the devices not substantially equivalent.

The following CAD/CAM workflow describes the steps involved to achieve the final prosthesis:

1. Utilizing a desktop dental scanner with the appropriate scan bodies, digitally capture the verified laboratory model, implant or abutment analog positions, soft tissue, and diagnostic wax-up.
2. Import the digital data into dental CAD software and utilize the corresponding implant library to design the bar within the design parameters per the instructions for use.
    a. If the customer is designing the bar, the design data is to be sent to a registered and listed BioHorizons-validated milling center for milling.
3. The BioHorizons-validated milling center will export the CAM data from the dental CAD/CAM software and proceed with milling the bar.
4. The milled bar is sent to the customer for the appropriate laboratory processing to create the final prosthesis.

The clinician delivers the final prosthesis intra-orally, verifies fit, and secures using the corresponding screws at the recommended torque values per the instructions for use.

The features, similarities and differences are further summarized in tabular format in the Summary Table of Substantial Equivalence following in this section, and are briefly discussed below:

1. Bar shapes for both the Subject Device and the predicate device are typical industry designs and are substantially equivalent.
2. Platform seating diameters of 3.0mm-5.7mm for the Subject Device, compared to 3.4mm-6.1mm of the predicate device, are based the manufacturers' designed implant platform geometries.
3. Minimum number of two (2) cylinders is equivalent.
4. Minimum cylinder wall thickness of 0.3mm for the Subject Device is based on design requirements; the predicate device specification is unknown.
5. Maximum anterior-posterior spread of 1.5 for the Subject Device is based on design requirements; the predicate device specification is unknown.
6. Maximum implant span between cylinders of 30mm for the Subject Device, compared to 23.5mm for Type I Bars and 27mm for Type II Bars of the predicate device, is based on the manufacturers' established design requirements.
7. Screw-retained mode of retention for both devices is equivalent.

The Subject Device worst case design was validated with performance bench testing in accordance with Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, May 12, 2004 and ISO 14801, and the differences noted or otherwise not accounted for by comparison to the predicate device are demonstrated by the performance bench testing, and do not render the Subject Device not substantially equivalent.

Summary of Testing

Dynamic mechanical fatigue testing 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. A worst-case 3.0mm prosthetic platform, single-unit endosseous dental implant system test configuration was prepared for the implant-level CAD/CAM bars to simulate a single bar cylinder being subjected to occlusal loading without the support of additional bar cylinders or supports/connectors to share the load. Results of the testing demonstrate that the worst-case configuration performs in accordance with the subject device's intended use. Evaluation of the abutment-level CAD/CAM bars was conducted by dimensional analysis of a cross-sectioned model of the CAD/CAM abutment-level bar configuration at least material condition (LMC) in the region of the implant-abutment connection compared to the BioHorizons Multi-unit Titanium Coping. Historical testing of the Multi-unit Titanium Coping combined with dimensional analysis demonstrated that the abutment-level CAD/CAM bar design is sufficient for its intended use.

Compatibility verification has been previously performed on a representative subset of Zimmer® Screw-Vent® and Tapered Screw-Vent® implants. The subset included the following Zimmer® item numbers: TSV4B8, TSV4B10, TSVWH10, TSVWB10, TSVWB11, TSVWH11, TSVT6B10, TSV6H11, TSV6H13 and TSV6H16. This testing verifies compatibility of BioHorizons CAD/CAM Bars connection with all Zimmer® Screw-Vent® and Tapered Screw-Vent® items based on equivalent mating platform geometry.

BioHorizons CAD/CAM Bars are provided non-sterile. Sterilization by the end user is achieved using one of the validated steam sterilization cycles as specified in the Instructions for Use. Sterilization cycles were validated in accordance with BS EN ISO 17665-1:2006, *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*.

Finally, BioHorizons CAD/CAM Bars 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 BioHorizons dental implant and restorative abutment 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**
	BioHorizons Implant Systems, Inc. CAD/CAM Bars	**Biomet 3i CAM StructSURE® Precision Milled Bars K080864**
Intended Use	BioHorizons CAD/CAM Bars are intended for use as superstructures of a multiple-unit endosseous dental implant system, attaching directly to implants or abutments in the mandible or maxilla, to support a prosthetic device in a partially or fully endentulous patient for the purpose of restoring chewing function. Implant-level bars are compatible with all BioHorizons Internal and Tapered Internal implant systems. Implant-level bars are compatible with Zimmer Dental Screw-Vent® and Tapered Screw Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex connection mating platform diameters and are intended to be used with straight bar cylinders only. Abutment-level bars are compatible with BioHorizons Multi-unit Abutments. All digitally designed BioHorizons CAD/CAM Bars are intended to be sent to a BioHorizons-validated milling center for manufacture.	The CAM StructSURE Precision Milled Bars are intended for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw retained.
Design		
Bar shape	Fixed shape (Dolder®, Hader, Round) Freeform shape (Freeform/Milled, Hybrid, Montreal, Paris, Wrap Around)	Type I (Dolder, Hader, Primary) Type II (Combination Primary, Hybrid, Wraparound, Freeform, Canada, Copymilled)
Platform seating diameter	3.0mm, 3.5mm, 4.5mm, 5.7mm	3.4mm – 6.1mm
Min. number of cylinders	2	2
Min. cylinder wall thickness	0.3mm	Not known
Max. anterior-posterior spread	1.5	Not known
Max. implant span	30mm	27mm (Type I) 23.5mm (Type II)
Mode of retention	Screw-retained	Screw-retained
Material and Manufacturing		
Bar material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136) or Grade 4 Titanium
Packaging	Poly/Tyvek pouch	Not known
Sterilization	Moist heat	Not known