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 13, 2016

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

Re: K151621
Trade/Device Name: BioHorizons CAD/CAM Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 11, 2015
Received: December 14, 2015

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

for 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 Statement
(as required by ODE for all 510(k)s received after January 1, 1996)

510(k) Number: K151621

Device Name: BioHorizons CAD/CAM Abutments

Indications for Use:

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.

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)

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: January 13, 2016

Name of the Device

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

Predicate Devices

Primary Predicate Device:
1. K122295, Core 3D Abutment System for Digital Prosthetic Solutions, October 24, 2013.

Reference Predicate Devices:
1. K111935, NT-Trading Ti-Base Abutment, 2-CONnect Abutment, February 17, 2012.
2. K103691, BioHorizons Abutments for Zimmer, November 3, 2011.
3. K121787, BioHorizons Tapered Internal Plus Implants, September 5, 2012.
4. K073268, BioHorizons Internal Implant System, February 8, 2008.
5. K071638, BioHorizons Tapered Internal Implant System, October 10, 2007.
6. K143022, BioHorizons Tapered Internal Implant System, January 8, 2015.
7. K013227, Zimmer® Dental (formerly Sulzer Dental) Screw-Vent® and Tapered Screw-Vent® Systems, November 19, 2001.

Device Description

BioHorizons CAD/CAM Abutments are dental implant final restorative abutments supplied in platform diameters of 3.0mm, 3.5mm, 4.5mm and 5.7mm. The abutments are intended to provide support for dental prosthetic restorations. Each abutment includes an abutment screw for fixation to the underlying implant. Abutment 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.*

Select abutments are further processed by applying patterns of micro-machined grooves or channels, known as Laser-Lok, to a specified region of the abutment margin. The abutments are provided non-sterile, and they are packaged using materials known in the industry to be appropriate for medical device packaging.

Indications for Use

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.

Technological Characteristics

The fundamental scientific technology of the BioHorizons CAD/CAM Abutments that are the subject of this 510(k) is substantially equivalent to the existing abutments of the referenced predicate devices. (Refer to the following Summary Table of Substantial Equivalence for comparison of the subject device to the declared predicate devices.) Select abutment models are further processed by applying Laser-Lok to a specified region of the abutment margin.

Both the subject device and predicate devices include similar design features such as abutment base material, surface treatment, implant-abutment connection tailored to the implant system(s) with which the devices are intended to be used, anti-rotational geometry, prosthetic platform sizes and mode of retention which thereby demonstrates substantial equivalence in their respective designs. Any specific differences related to prosthetic platform sizes between the subject device and the predicate devices do not raise questions of safety or effectiveness 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 features, similarities and differences are further summarized in tabular format in Table 1. Summary Table of Substantial Equivalence following in this section. The Zimmer compatible platforms are identical to the declared predicate, K103691. The BioHorizons 3.0mm platform compatible implant is identical to the declared predicate device cleared in K143022. The compatible platform implants are substantially equivalent to the declared predicates.

All materials, suppliers and packaging methods remain the same as those utilized for the predicate BioHorizons Abutments for Zimmer (K103691). Additionally, the Laser-Lok feature is substantially equivalent to that cleared for the BioHorizons Abutments for Zimmer (K103691). The BioHorizons CAD/CAM Abutments are substantially equivalent to the features of the predicate abutment devices which could affect safety or effectiveness because of the similarities in design, materials and intended use.

Abutment Manufacturing

A custom abutment design file is created by the customer using a 3Shape abutment library. The abutment design file is converted to a stereolithography (.stl) file using 3Shape software. The .stl file is converted to a numerical control (.nc) file using an appropriate software application (e.g.

SUM3D). After the custom abutment design is uploaded, the milling machine software executes the necessary commands to mill the final abutment. The digitally designed file is to be sent to a registered and listed BioHorizons contract manufacturer for milling. BioHorizons CAD/CAM Abutments are compatible with commercially available dental CAD/CAM systems, such as 3Shape.

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. Results of the testing demonstrate that the fully milled, worst-case 30° angled configurations of both the 3.0mm and 3.5mm prosthetic platform abutments and the titanium bases with bonded zirconia superstructure perform in accordance with their intended use.

Compatibility testing was 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 Abutments for Zimmer® with all Zimmer® Screw-Vent® and Tapered Screw-Vent® items based on equivalent mating platform geometry.

Steam sterilization validation testing was performed new in accordance with AAMI/ANSI/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*. Test results demonstrate a sterility assurance level (SAL) of 10^{-6}.

Finally, software intended use validation testing of the software systems utilized in the manufacture of the CAD/CAM abutments was performed to ensure that the program design limitations prevent the user from milling abutments that do not fulfill the BioHorizons design criteria.

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. BioHorizons CAD/CAM Abutments	**Core 3D Abutment System for Digital Prosthetic Solutions K122295**	**NT-Trading Ti-Base Abutment, 2-CONnect Abutment K111935**	**BioHorizons Implant Systems, Inc. BioHorizons Abutments for Zimmer K103691**
Classification/ Product Code	872.3630/NHA	872.3630/NHA	872.3630/NHA	872.3630/NHA
Intended Use	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.	The CORE 3D abutment system for digital prosthetic solutions are dental abutments placed into a dental implant to provide support for dental prosthetic restorations. The abutments include: • Titanium Bases to be attached to the underlying implant and upon which a CAD/CAM designed superstructure may be fitted to complete a two-piece dental abutment; • 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; • Abutment Screws to permanently fix the abutments to the underlying implant. Core 3D abutments are intended for use to support single-tooth (unit) and multiple-tooth (bridges and bars) prostheses, in the mandible or maxilla for functional and aesthetic restorations. Core 3D abutments designed using CAD/CAM techniques must fulfill the Core 3D allowable range of design specifications and be provided as straight abutments only. Core 3D abutments and are compatible for use with the following dental implants: • Nobel Biocare® Branemark System™ (K022562, K934825) • Zimmer® Tapered Screwvent® (K013227, K061410, K072589)	Ti-Base for individual Zirconium Abutments: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The Ti-Base for individual Zirconium Abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Ti-Base abutments are indicated for use with the following implant systems: • Nobel Biocare® Replace Select® • Nobel Biocare No be !Active ™ • Biomet 3i® Osseotite® • Biomet 3i® Osseotite® Certain® • Nobel Biocare Branemark® • Straumann® synOcta® • Straumann® Bone Level® • Zimmer® Tapered Screw-vent® • Astra Tech OsseoSpeed® • Dentsply-Friadent® Frialit® 2-CONnect Abutment for Bridges and Bars: 2-CONnect Abutment for Bridges and Bars is indicated for use to provide support for prosthetic restorations such as bars and bridges. The 2-CONnect abutments can be used in multiple tooth restorations. The 2-CONnect abutment can be used together with cemented bridges and bar constructions for functional and aesthetical reconstruction. The 2-CONnect abutments are indicated for use with the following implant systems: • Nobel Biocare® Replace Select® • Straumann® synOcta® • Straumann® BoneLevel®	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.

Table 1. Summary Table of Substantial Equivalence (cont.)

	Subject Device	Primary Predicate Device	Reference Predicate Devices	
	BioHorizons Implant Systems, Inc. BioHorizons CAD/CAM Abutments	**Core 3D Abutment System for Digital Prosthetic Solutions K122295**	**NT-Trading Ti-Base Abutment, 2-CONnect Abutment K111935**	**BioHorizons Implant Systems, Inc. BioHorizons Abutments for Zimmer K103691**
Design				
Surface	All abutments (except 3.0mm platform): Anodized on the hex connection Select abutments: TiN coated; Laser-Lok in specified zone between prosthetic margin and the implant-abutment junction (IAJ)	Not known	Not known	All abutments: Anodized on the hex connection Select abutments: TiN coated; Laser-Lok in specified zone between prosthetic margin and the implant-abutment junction (IAJ)
Laser-Lok Zone	Groove size: 8µm width and depth Min. height (vertical dimension): 0.5mm	N/A	N/A	Groove size: 8µm width and depth Min. height (vertical dimension): 0.5mm
Connection	Internal Hex	Varies, External and Internal dependent on implant system compatibility	Varies, dependent on implant system compatibility	Internal Hex
Prosthetic platform	3.0mm, 3.5mm, 4.5mm, 5.7mm	3.5mm, 4.1mm, 4.5mm, 5.1mm, 5.7mm	3.5mm (minimum), 6.5mm (maximum)	3.5mm, 4.5mm, 5.7mm
Angulation	Custom Ti (blanks): 0°-30° Ti Base (ceramic): 0°-20°	Not known	Not known	0°-20°
Abutment Screw Included	Yes	Yes	Yes	Yes
Mode of retention	Screw-retained to the implant; the prosthesis can be cement retained to the abutment	Screw-retained to the implant; the prosthesis can be cement retained to the abutment	Screw-retained or cement retained	Screw-retained to the implant; the prosthesis can be cement retained to the abutment
Material and Packaging				
Abutment Material	Ti-6Al-4V (ASTM F136); additionally, Y-TZP Ceramic for Titanium Base Abutment	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V (ASTM F136), Gold Alloy 6019, Y-TZP Ceramic, PEEK
Packaging	Poly/Tyvek pouch	Not known	Not known	Sterile Abutments: Ploy/Tyvek pouch inside plastic support tub Non-sterile Abutments: Poly/Tyvek pouch

Table 2. BioHorizons and Zimmer Implant Compatibility Table

	Subject Device	Compatible Implant Devices			
	BioHorizons Implant Systems, Inc. BioHorizons CAD/CAM Abutments	**BioHorizons Implant Systems, Inc. Tapered Internal Plus Implants K121787**	**BioHorizons Implant Systems, Inc. Internal Implant System K073268**	**BioHorizons Implant Systems, Inc. Tapered Internal Implant System K071638 & K143022**	**Zimmer® Dental (formerly Sulzer Dental) Screw-Vent® and Tapered Screw-Vent® Systems K013227**
Design					
Implant Body Diameter	N/A	3.8mm, 4.6mm, 5.8mm	3.5mm, 4.0mm, 5.0mm, 6.0mm	3.4mm, 3.8mm, 4.6mm, 5.8mm	3.3mm, 3.7mm, 4.1mm, 4.7mm, 6.0mm
Implant length	N/A	7.5mm (except 3.8mm body), 9mm, 10.5mm, 12mm, 15mm	9mm, 10.5mm, 12mm, 15mm	7.5mm (except 3.8mm body), 9mm, 10.5mm, 12mm, 15mm, 18mm (except 5.8mm body)	8mm, 10mm, 11.5mm, 13mm, 16mm
External thread	N/A	Buttress	Square	Buttress	V-shaped (Triple-Lead Thread)
Surface	All abutments (except 3.0mm platform): Anodized on the hex connection Select abutments: TiN coated; Laser-Lok in specified zone between prosthetic margin and the implant-abutment junction (IAJ)	Implant - RBT Collar - Laser-Lok	Implant - RBT or HA Collar - Laser-Lok or RBT	Implant - RBT or HA Collar - Laser-Lok or RBT	Implant - MTX Microtexture or HA Collar - Machined
Connection	Internal Hex	Internal Hex	Internal Hex	Internal Hex	Internal Hex
Internal thread	N/A	Spiralock UNF 1-72	Spiralock UNF 1-72	Spiralock UNF 1-72	UNF 1-72
Prosthetic platform	3.0mm, 3.5mm, 4.5mm, 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
Material and Manufacturing					
Material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Titanium (commercially pure)
Manufacturing process	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, anodized for color, collar micro-machined with grooves, threaded surface treated with RBT, passivated per ASTM F86	Machined by BioHorizons or A-level supplier, anodized for color, collar micro-machined with grooves, threaded surface treated with RBT or HA, passivated per ASTM F86	Machined by BioHorizons or A-level supplier, anodized for color, collar micro-machined with grooves, threaded surface treated with RBT or HA, passivated per ASTM F86	Not known
Packaging	Poly/Tyvek pouch	Tyvek-lidded blister tray	Tyvek-lidded blister tray	Tyvek-lidded blister tray	Plastic vial with tamper-evident cap
Sterilization	N/A; provided non-sterile, steam sterilization in accordance with qualified cycles as specified in the Instructions for Use	25-40 kGy gamma irradiation dose range	25-40 kGy gamma irradiation dose range	25-40 kGy gamma irradiation dose range	Gamma irradiation; dose range not known