October 13, 2023

BioHorizons Implant Systems, Inc.
Jared Cooper
Director, Regulatory Affairs
2300 Riverchase Center
Birmingham, Alabama 35244

Re: K223697
Trade/Device Name: MRI compatibility for existing BioHorizons dental implants and abutments
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 19, 2023
Received: September 20, 2023

Dear Jared Cooper:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223697

Device Name
MRI compatibility for existing BioHorizons dental implants and abutments

Indications for Use *(Describe)*
BioHorizons 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. 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.

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 3.0, Tapered Tissue Level 3.0, and Laser-Lok 3.0 Implants may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion, (2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or (3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.

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)

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510(k) Number *(if known)*
K223697

Device Name
MRI compatibility for existing BioHorizons dental implants and abutments

Indications for Use *(Describe)*
Intra-Lock 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. 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.

Intra-Lock 3.3mm diameter implants may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion, (2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or (3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.

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)

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Device Name
MRI compatibility for existing BioHorizons dental implants and abutments

Indications for Use *(Describe)*
Mini Drive-Lock™ Dental Implants are intended for use as a self-tapping titanium screw for transitional or intra-bony long-term applications.

Mini Drive-Lock™ Dental Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants should be used and may be restored after a period of time or placed in immediate function.

MILO™ Dental Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants may be restored after a period of time or placed in immediate function. They are also indicated for the rehabilitation of single maxillary lateral incisors and mandibular lateral and central incisors. The implants may be restored after a period of time or placed in immediate function.

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)

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510(k) Number *(if known)*
K223697

Device Name
MRI compatibility for existing BioHorizons dental implants and abutments

Indications for Use *(Describe)*
BioHorizons Prosthetics 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 as straight abutments.

The BioHorizons Multi-unit Abutments for CONELOG® are intended to function in the mandible or maxilla to support single and multiple-unit temporary or definitive restorations on CONELOG dental 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)

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510(k) Number *(if known)*
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Device Name
MRI compatibility for existing BioHorizons dental implants and abutments

Indications for Use *(Describe)*
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.

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)

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Food and Drug Administration

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510(k) Number *(if known)*
K223697

Device Name
MRI compatibility for existing BioHorizons dental implants and abutments

Indications for Use *(Describe)*
Intra-Lock Prosthetics 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 Intra-Lock implants.

Intra-Lock Titanium Base Abutments and Laser-Lok Titanium Base Abutments are intended to be used as straight abutments.

Intra-Lock 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 Intra-lock implants. All digitally designed abutments and/or copings for use with Intra-Lock CAD/CAM Abutments are intended to be sent to a BioHorizons-validated milling center for manufacture. Intra-Lock abutments designed using CAD/CAM techniques must fulfill the BioHorizons allowable range of design parameters.

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

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Device Name
MRI compatibility for existing BioHorizons dental implants and abutments

Indications for Use *(Describe)*
The MILO and Mini Drive Lock Implant System Prosthetics have been designed to restore partially or fully edentulous patients. The abutments have been designed to be used in either the mandible or maxilla and to support removable or fixed prosthesis.

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

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