June 26, 2026

BioHorizons Implant Systems, Inc.
Amanda Hatley
Regulatory Affairs Associate II
2300 Riverchase Center
Birmingham, Alabama 35244

Re: K260061
Trade/Device Name: BioHorizons CEREC Compatible Ti-Bases
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: May 29, 2026
Received: May 29, 2026

Dear Amanda Hatley:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260061

Device Name
BioHorizons CEREC Compatible Ti-Bases

Indications for Use *(Describe)*

Chairside Ti-Bases

BioHorizons Chairside Ti-Bases connected to the endosseous dental implants are intended for use as an aid in prosthetic rehabilitations of the maxillary or mandibular arch to provide support for prosthetic restorations.

BioHorizons 3.0 Chairside Ti-Bases are limited for use as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors when used with 3.4mm diameter implants.

All digitally designed abutments and/or copings for use with Chairside Ti-Bases are to be designed using Sirona CEREC® Software and manufactured using a Sirona CEREC® MC XL milling unit.

Conical CEREC Compatible Ti Bases

Conical CEREC Compatible Ti Bases connected to the endosseous dental implants are intended for use as an aid in prosthetic rehabilitations of the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed abutments and/or copings for use with Conical CEREC Compatible Ti Bases are to be designed using Sirona CEREC® Software and manufactured using a Sirona CEREC® MC XL milling unit.

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
BioHorizons Implant Systems Inc.
CEREC Compatible Ti-Bases
June 25, 2026

ADMINISTRATIVE INFORMATION

Manufacturer Name	BioHorizons Implant Systems Inc. 2300 Riverchase Center Birmingham, AL 35244 Telephone +1 205-967-7880 Fax +1 205-870-0304
Official Contact	Amanda Hatley Regulatory Affairs Associate II ahatley@biohorizons.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	BioHorizons CEREC Compatible Ti-Bases
Common Names	Endosseous dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA, PNP
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1B (Dental and ENT Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device—*Chairside Ti-Bases & Conical CEREC Compatible Ti Bases*
K240187, BioHorizons Tapered Pro Conical Implant System (TPC)

Reference Device— *Chairside Ti-Bases & Conical CEREC Compatible Ti Bases*
K171532, TruBase S

Reference Device—*Chairside Ti-Bases & Conical CEREC Compatible Ti Bases*
K250295, Dentsply Sirona Titanium Bases system

Reference Device—*Chairside Ti-Bases*
K223697, MRI compatibility for existing BioHorizons dental implants and abutments.

Reference Device—*Chairside Ti-Bases*
K151621, BioHorizons CAD/CAM Abutments

Reference Device—*Chairside Ti-Bases & Conical CEREC Compatible Ti Bases*
K143337, CONELOG Titanium Base CAD/CAM

Reference Device—*Chairside Ti-Bases & Conical CEREC Compatible Ti Bases*
K193408, Sirona Dental CAD/CAM System with CEREC Chairside Software

Reference Device—*Chairside Ti-Bases & Conical CEREC Compatible Ti Bases*
K234018, CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System

Reference Device—*Chairside Ti-Bases & Conical CEREC Compatible Ti Bases*
K022476, RELYX RMGIP

INDICATIONS FOR USE STATEMENT

Chairside Ti-Bases

BioHorizons Chairside Ti-Bases connected to the endosseous dental implants are intended for use as an aid in prosthetic rehabilitations of the maxillary or mandibular arch to provide support for prosthetic restorations.

BioHorizons 3.0 Chairside Ti-Bases are limited for use as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors when used with 3.4mm diameter implants.

All digitally designed abutments and/or copings for use with Chairside Ti-Bases are to be designed using Sirona CEREC® Software and manufactured using a Sirona CEREC® MC XL milling unit.

Conical CEREC Compatible Ti Bases

Conical CEREC Compatible Ti Bases connected to the endosseous dental implants are intended for use as an aid in prosthetic rehabilitations of the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed abutments and/or copings for use with Conical CEREC Compatible Ti Bases are to be designed using Sirona CEREC® Software and manufactured using a Sirona CEREC® MC XL milling unit.

SUBJECT DEVICE DESCRIPTION

The purpose of this premarket notification is to obtain marketing clearance for two new BioHorizons CEREC Compatible Ti-Bases. One is the Chairside Ti-Base, which expands the BioHorizons Ti-Base Abutment portfolio (internal hex connection), and the other is the Conical CEREC Compatible Ti Base, which expands the BioHorizons Tapered Pro Conical (TPC) Implant System portfolio (deep conical connection). The TPC Implant System cleared in **K240187** serves as the primary predicate device for this submission. The introduction of these devices will also include Instructions for Use within the Sirona CEREC® workflow (**K171532**).

The subject Chairside Ti-Base abutments will have internal hex connections available in sizes 3.0mm, 3.5mm, 4.5mm, and 5.7mm offered in gingival heights of 1mm, 2mm, and 3mm. Chairside Ti-Bases are intended for the restoration of BioHorizons Dental Implants within the specific indications of each implant system. Note: BioHorizons 3.0 Chairside Ti-Bases are contraindicated for use with 3.0mm diameter implants. Also, Tapered Tissue Level implants are not intended for use with the Chairside Ti-Bases.

The subject Conical CEREC Compatible Ti Base abutments will have conical connections available in sizes Narrow and Regular and offered in gingival heights of 0.8mm and 2mm. The subject CEREC Compatible Ti Bases, are intended for the restoration of BioHorizons Conical Dental Implants within the specific indications of each implant system.

BioHorizons CEREC Compatible Ti-Bases are designed to connect with BioHorizons dental implants to enable prosthetic restoration of edentulous areas within the oral cavity. BioHorizons internal hex implant to abutment connection has been used since 2004 (**K042429)** and most recently cleared in reference predicate **K223697**. However, the original clearance of the BioHorizons CAD/CAM Ti-Base abutments with the internal hex implant to abutment connection is in **K151621**. These Ti-Base titanium components are extraorally cemented to patient-specific zirconia blocks, creating a complete two-piece hybrid abutment system. In this configuration, the lower portion of the abutment is the Ti-Base titanium component, which engages the implant's system-specific geometry, while the upper portion consists of a zirconia abutment block that is milled to form either an abutment crown or a mesostructure, the latter subsequently finished with a crown. The Ti-Base titanium component serves as the platform for bonding the customized milled component, resulting in the complete Sirona CEREC® Ti-Base system abutment, which is secured to the dental implant using an abutment screw.

Fabrication of all patient-specific custom abutments for Ti-Base systems is performed by prescription based on the clinician's order. Because the CEREC® workflow is a 510(k)-cleared (**K143337**) self-contained milling solution, zirconia superstructures used with BioHorizons CEREC-Compatible Ti-Bases follow a single pathway: Sirona CEREC® workflow.

For the subject device, BioHorizons CEREC Compatible Ti-Bases incorporates a two-piece hybrid abutment configuration consisting of a BioHorizons titanium base manufactured from Ti-6Al-4V alloy (ASTM F136) and a zirconia superstructure (CEREC Cercon 4D™ Abutment Blocks, **K234018**) bonded using 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement (**K022476**). The proposed Ti-Base titanium components are assembled through extraoral cement bonding (3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement (**K022476)** with the patient specific CEREC Cercon 4D™ Abutment Block (**K234018**), to form the complete, two-piece CAD/CAM Titanium Base system abutments. This configuration – Ti-Base titanium component with the CEREC Cercon 4D™ Abutment Blocks (**K234018**), within the Sirona CEREC system – is not novel in design and is FDA-cleared per **K250295**. Note: The only difference between the subject and predicate (**K250295**) configurations is the bonding agent between the Ti-Base titanium component and zirconia block. The subject device uses 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement cleared in **K022476** while the predicate, *Denstply Sirona Titanium Bases System* (**K250295**), uses Calibra® Abutment Resin Cement (**K240888**). Both bonding agents have a history of use and are FDA-cleared dental resin cements intended for extraoral bonding of abutment components.

For compatibility within the Sirona CEREC workflow, the top half (cementable post) geometry of the subject Ti-Base titanium components which is conserved across all BioHorizons CEREC Compatible Ti-Bases, is a cleared cementable post geometry by **K143337**, *CONELOG Titanium CAD/CAM* (designed by partner company Altatec GmbH). Therefore, because the post geometries of all subject devices, Chairside Ti-Bases and Conical CEREC Compatible Ti Bases, are equivalent in post geometries to the previously cleared abutments currently used in the Sirona CEREC workflow, (cleared under **K193408**, *Sirona Dental*

System with CEREC Chairside Software), the subject devices do not introduce any new worst cases and are compatible in the Sirona CEREC Workflow.

It is important to note that parameters are pre-determined in the Sirona CEREC workflow system. The angulation within is also fixed and set across all libraries. If the user chooses an angulation outside the set value, they will receive an error screen that is red in color that indicates a "stop" and the user will not be able to proceed without updating the design to meet the angulation set within the system. The following design parameters in the Sirona CEREC® workflow **(K234018)** are as follows:

- Abutment Post height ≥ 4.0 mm
- 20° maximum post angulation
- 0.5 mm minimum wall thickness

The wall thickness parameter is defined in the Sirona CEREC software library for the material itself. If the user chooses a wall thickness outside the defined parameter, they will receive an error screen and will not be able to proceed without updating the design to meet the wall thickness parameter.

Performance verification testing has been completed to support the BioHorizons subject abutments and compatible implants following FDA recognized consensus standard ISO 14801, *Dentistry – Implants – Dynamic load testing for endosseous dental implants*.

MATERIAL COMPOSITION

The subject devices are manufactured from Ti-6Al-4V alloy per ASTM F136, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications,* and a superstructure manufactured from CEREC Cercon 4D™ Abutment Blocks using CEREC Cercon 4D™ Abutment System Multidimensional Ceramic Zirconia (**K234018**) which is bonded using 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement (**K022476**). The BioHorizons CEREC Compatible Ti-Bases are for single patient use and are provided non-sterile as indicated on the label. The subject devices are permanent or long-term, tissue/bone implant devices intended for more than 30 days of patient contact. BioHorizons dental prosthetics are invasive and/or surgically invasive devices placed in healed or compromised oral sites in direct contact with bone and soft tissue.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included:

- Validation of the recommended moist heat sterilization cycle by the overkill method to a sterility assurance level (SAL) of 10^{-6} according to ISO 17665-1 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices, and ISO/TR 17665-2 Sterilization of health care products – Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1.
- Biocompatibility testing of samples representing all subject device materials and manufacturing processes according to ISO 10993-1 Biological evaluation of medical devices, leveraged from the reference predicate device **K223697 -** *MRI compatibility for existing BioHorizons dental implants and abutments* and **K240187 –** *BioHorizons Tapered Pro Conical Implant System (TPC).*
- Biocompatibility testing of samples representing all subject device materials and manufacturing processes according to ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- Magnetic Resonance Imaging (MRI) testing according to ASTM 2052 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic

Resonance Environment, leveraged from the primary predicate device **K240187 –** *BioHorizons Tapered Pro Conical Implant System (TPC)* and reference predicate device **K223697 -** *MRI compatibility for existing BioHorizons dental implants and abutments.*

- Distribution testing of packaging configuration to meet standard ASTM D4169-16 – Standard Practice for Performance Testing of Shipping Containers and Systems, leveraged from the reference predicate device **K223697 -** *MRI compatibility for existing BioHorizons dental implants and abutments* and primary predicate device **K240187 –** *BioHorizons Tapered Pro Conical Implant System (TPC).*
- Mechanical testing according to ISO 14801:2016 Dentistry – Implants – Dynamic loading test for endosseous dental implants.
    - Four test conditions were run at 2Hz to achieve runout of 2 million cycles; final abutments using CEREC Cercon 4D™ Abutment Blocks cemented using 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement on both Chairside Ti-Bases and Conical CEREC Compatible Ti Bases.
- Validation of Sirona CEREC® System compatibility to ensure geometry of Chairside Ti-Bases mates with corresponding CEREC® CAD/CAM materials.

No clinical data was included in this submission.

EQUIVALANCE TO MARKETED DEVICES

All BioHorizons CEREC Compatible Ti Bases are substantially equivalent in Indications for Use and design principles to each of their primary and/or reference predicates listed above. Provided at the end of this summary are tables (**Table 1** and **Table 2**) comparing the Indications for Use Statements and the technological characteristics of the subject device to the primary predicate device and the reference predicate devices.

Substantial Equivalence of Intended Use and Indications for Use Statement (IFUs)
The subject BioHorizons CEREC Compatible Ti Bases are identical in intended use to the primary predicate cleared in **K240187.**

The subject Chairside Ti-Bases and Conical CEREC Compatible Ti Bases incorporate Indications for Use from previously cleared abutments under **K223697** and **K240187**, respectively, with an expansion to include CEREC compatibility (**K171532)**. The expansion indicates that all BioHorizons CEREC Compatible Ti-Bases may be used within a Sirona CEREC® workflow including Sirona CEREC® software, zirconia, and milling units, which is substantially equivalent to the *TruBase S* abutment cleared in **K171532**. Note: The Indications verbiage for Chairside Ti Bases is slightly different than the verbiage for Conical CEREC Compatible Ti Bases. In an effort to be consistent, Chairside Ti Base verbiage will be adjusted to align with the Conical CEREC Compatible Ti Base verbiage (**K240187)**. The expanded Indications for both the Chairside Ti-Bases and the Conical CEREC Compatible Ti Bases will be reflected in a standalone IFU specific to each Ti-Base.

The minor differences between the subject and predicate device(s) Indications for Use do not impact substantial equivalence because all IFUs express equivalent intended use to facilitate functional and esthetic rehabilitation of the edentulous mandible or maxilla.

Substantial Equivalence of Technological Characteristics
All BioHorizons CEREC Compatible Ti Bases are substantially equivalent in design, materials and technological characteristics to corresponding abutments of the primary (**K240187)** or reference (**K171532** and **K250295)** predicate devices. Note that the Chairside Ti-Bases use the BioHorizons internal hex implant to abutment connection used since 2004 (**K042429**) and most recently cleared in **K223697.** Also, the

original clearance of the internal hex within the BioHorizons CAD/CAM Abutment two-piece configuration is in **K151621**. The BioHorizons CAD/CAM Abutments cleared in **K151621** are identical to the subject Chairside Ti-Bases in technology, materials, prosthetic platform sizes, processing, sterilization, and shelf-life.

The Chairside Ti-Base Abutments and Conical CEREC Compatible Ti Bases, are substantially equivalent to these predicates in fit and function and introduce no new risks to the safety or effectiveness of the devices. The subject Chairside Ti-Bases, the Conical CEREC Compatible Ti Bases, and primary predicate devices are manufactured from the same material, are provided non-sterile, have the same intended use and have similar indications for use (with the additional information the subject devices are adding from the reference predicates to be compatible in the Sirona CEREC® workflow). See **Table 1** and **Table 2** below for further details of the Indications for Use comparisons.

The Chairside Ti-Bases are not novel in design and are substantially equivalent to cleared devices already on the market (i.e., **K240187, K143337, K171532, K193408, K223697,** and **K151621)**. The proposed Chairside Ti-Base with internal hex implant/abutment connection uses the same design as the one Dentsply Sirona (**K193408**) incorporated for BioHorizons' internal hex implant/abutment geometry, which was most recently cleared under **K223697**. Additionally, **K250295** lists BioHorizons Internal Hex Implants (**K223697**) in its compatibility chart, confirming that the exact implant interface and Ti-Base titanium component geometry of the BioHorizons subject device has already been cleared for use within the Sirona CEREC workflow. As for the post geometry and compatibility within the Sirona CEREC workflow, the top half (cementable post) geometry of the subject Ti-Base titanium components which is conserved across all BioHorizons CEREC Compatible Ti-Bases, including Chairside Ti-Bases, is a cleared cementable post geometry by **K143337**, *CONELOG Titanium CAD/CAM with CEREC Software*. Therefore, the subject Chairside Ti-Base Abutments, using the identical internal hex implant/abutment connection (**K223697, K151621,** and **K193408)** and identical cementable post geometry (**K143337**), are substantially equivalent to the previously cleared devices and are compatible within the Sirona CEREC workflow.

The design of the Ti-Base titanium component of the subject Conical CEREC Compatible Ti Bases is identical to the previously marketed Conical Ti Base Abutments cleared in **K143337**, *CONELOG Titanium CAD/CAM with CEREC Software.* Thus, the design of the post geometry, the diameters, and the emergence heights do not introduce any new worst-cases. Also, because the subject Conical CEREC Compatible Ti Base titanium components are identical to the predicate abutments (**K143337**) previously cleared for use within the Sirona CAD/CAM system, it is concluded that the subject device is likewise compatible with the Sirona CAD/CAM System (**K193408**). Therefore, additional verification testing is not required, and the subject devices are compatible within the Sirona CEREC workflow.

The subject CEREC Compatible Ti-Base titanium components are provided non-sterile and have packaging that consists of Tyvek and polyethylene terephthalate (PET)/ low density polyethylene (LDPE) pouches. This packaging is identical to that used for corresponding products cleared in predicate submissions, **K223697** and **K240187**.

The subject CEREC Compatible Ti-Bases are sterilized using moist heat sterilization cycles validated by the overkill method to a sterility assurance level (SAL) of 10^{-6} according to ISO 17665-1 *Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*, and *ISO/TR 17665-2 Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1*. The moist heat sterilization process used for the subject devices is identical to the process used for the predicate devices cleared under **K240187**.

Any differences in the technological characteristics between the subject device, primary predicate and/or reference devices do not introduce any new risks to the safety or effectiveness of the subject device. The data included in this submission for the subject device demonstrates substantial equivalence to the primary predicate and reference devices listed above.

Overall, the subject device has the following similarities to the primary predicate device and the reference devices:

- has the same intended use
- uses the same operating principles
- incorporates the same basic designs
- incorporates the same materials
- has the same packaging and is cleaned and sterilized using the same materials and processes
- has the same use within a digital dentistry workflow

The basis for the belief of BioHorizons Implant Systems Inc. that the subject device, BioHorizons CEREC Compatible Ti-Bases, is substantially equivalent to the predicate devices is summarized in the following table.

Table 1: Substantial Equivalence for Chairside Ti-Base Abutments

Attributes	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device
Trade Name	**Chairside Ti-Base**	**BioHorizons Tapered Pro Conical Implant System (TPC) (K240187)**	**TruBase S (K171532)**	**Dentsply Sirona Titanium Bases system (K250295)**
Reason for selection	Subject Device	Primary Predicate for intended use, design, implant abutment connection (for Conical CEREC Compatible Ti Bases), technology, materials, processing, sterilization, and shelf-life	Reference Predicate for Indications for Use for Sirona CEREC® workflow Compatibility	Reference Predicate for a BioHorizons Ti-Base with CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System Multidimensional Zirconia material, within the Sirona CEREC® workflow
Indications for Use	BioHorizons Chairside Ti-Base connected to the endosseous dental implants are intended for use as an aid in prosthetic rehabilitations of the maxillary or mandibular arch to provide support for prosthetic restorations. BioHorizons 3.0 Chairside Ti-Bases are limited for use as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors when used with 3.4mm diameter implants. All digitally designed abutments and/or copings for use with Chairside Ti-Bases are to be designed using Sirona CEREC® Software and manufactured using a Sirona CEREC® MC XL milling unit. **(Substantially equivalent in Indications for Use to predicate(s))**	BioHorizons conical dental prosthetic components connected to the endosseous dental implants are intended for use as an aid in prosthetic rehabilitations of the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed abutments for use with Conical CAD/CAM Ti Blanks and Ti All Bases are to be sent to a BioHorizons validated milling center for manufacture.	TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems: • Zimmer TSV- 3.7, 4.1, 4.7, 6.0mm 3.5, 4.5, 5.7mm platform sizes) All digitally designed abutments and/or coping for use with the TruBase S are to be designed using Sirona inLab software or Sirona CEREC Software and manufacture using a Sirona CEREC or inLab MCX or MC XL milling unit.	The Dentsply Sirona Titanium Bases system is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. For AT EV 3.0 S, AT TX 3.0 S, BH 3.0 S, and SB L 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system comprises three parts: Abutment Block material (CEREC Cercon 4D™ • Abutment Block) • Titanium Base (TiBase) • CAD/CAM system The TiBase is recommended for use with two-piece hybrid abutments and hybrid abutment crowns, used in conjunction with endosseous dental implants.
Product Code	NHA, PNP **(Identical Product Codes to predicate)**	NHA	NHA	NHA, PNP
Abutment Margin Diameter(s)	Engaging: 3.9mm, 4.3mm, 4.8mm, 6.0mm, **(Substantially equivalent in Abutment Diameter(s) to predicate(s))**	Engaging: 4mm, 4.5mm	4.3mm, 5.3mm, 6.5mm	Unknown

Attributes	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device
Trade Name	**Chairside Ti-Base**	**BioHorizons Tapered Pro Conical Implant System (TPC) (K240187)**	**TruBase S (K171532)**	**Dentsply Sirona Titanium Bases system (K250295)**
Ti-Base titanium component Height(s)	4.7mm **(Identical Ti-Base titanium component Height(s) to predicate)**	≥ 4 mm	4.7mm	≥ 4 mm
Ti-Base titanium component Gingival Height(s)	1mm, 2mm, and 3mm **(Identical Ti-Base titanium component Gingival Height(s) to predicate)**	0.8mm, 2mm	0.8mm, 1mm, 8mm, 2.8mm, and 3.8mm	1mm, 2mm, and 3mm
Material of Ti-Base titanium component	Ti-6Al-4V alloy **(Identical Material of the Ti-Base titanium component to primary predicate)**	Ti-6Al-4V alloy	Ti-6Al-4V ELI	Titanium alloy (Ti6Al4V)
Implant-to-Abutment Connection(s)	Internal Hex **(Identical Implant-to-Abutment Connections(s) to predicates)**	Conical, engaging	Internal Hex	Internal Hex
Type of Retention	Screw-retained **(Identical Type of Retention to primary predicate)**	Screw-retained	Screw-retained	Unknown
Restorative Range of Angulation	Up to 20° **(Identical Restorative Range of Angulation to primary predicate)**	Up to 20°	Up to 20°	0 to 20°
Material of Superstructure	CEREC Cercon 4D™ (**K234018**) bonded using 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement (**K022476**) **(Identical Material of Superstructure to predicate(s))**	sagemax NexxZr zirconia (**K130991**) bonded using 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement (**K022476**) or similar	inCoris ZI meso (**K123664**)	CEREC Cercon 4D™ (**K234018**)
Patient-Specific Design	CAD/CAM manufactured superstructures **(Identical Patient-Specific Design to primary predicate)**	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures
Manufacturing Workflow	Sirona Dental CAD/CAM System Sirona CEREC® workflow **(Identical Manufacturing workflow to predicate(s))**	Validated Milling Center	Sirona Dental CAD/CAM System	Design and manufacture of top half of abutment performed by clinician/lab in CAD/CAM software system cleared in **K193408** The CAD/CAM system incorporates the TiBases which allows for design of the top half of the abutment.

Attributes	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device
Trade Name	**Chairside Ti-Base**	**BioHorizons Tapered Pro Conical Implant System (TPC) (K240187)**	**TruBase S (K171532)**	**Dentsply Sirona Titanium Bases system (K250295)**
End-User Sterilization	Moist steam sterilization **(Identical Sterilization to primary predicate)**	Moist steam sterilization	Moist steam sterilization	Provided non-sterile (to be steam sterilized)
Shelf-Life	N/A **(Identical Shelf-Life to Primary Predicate)**	N/A	N/A	N/A
MRI Compatibility	MR Conditional **(Identical MRI Compatibility to Primary Predicate)**	MR Conditional	MR Conditional	MR Conditional
Biocompatibility	Biocompatible per ISO 10993-1 **(Identical Biocompatibility to Primary Predicate)**	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1

Table 2: Substantial Equivalence for Conical CEREC Compatible Ti Bases

Attributes	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device
Trade Name	**Conical CEREC Compatible Ti Bases**	**BioHorizons Tapered Pro Conical Implant System (TPC) (K240187)**	**TruBase S (K171532)**	**Dentsply Sirona Titanium Bases system (K250295)**
Reason for selection	Subject Device	Primary Predicate for intended use, design, implant abutment connection (for Conical CEREC Compatible Ti Bases), technology, materials, processing, sterilization, and shelf-life	Reference Predicate for Indications for Use for Sirona CEREC® workflow Compatibility	Reference Predicate for a BioHorizons Ti-Base with CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System Multidimensional Zirconia material, within the Sirona CEREC® workflow
Indications for Use	Conical CEREC Compatible Ti Bases connected to the endosseous dental implants are intended for use as an aid in prosthetic rehabilitations of the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed abutments and/or copings for use with Conical CEREC Compatible Ti Bases are to be designed using Sirona CEREC® Software and manufactured using a Sirona CEREC® MC XL milling unit. **(Substantially equivalent in Indications for Use to predicate(s))**	BioHorizons conical dental prosthetic components connected to the endosseous dental implants are intended for use as an aid in prosthetic rehabilitations of the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed abutments for use with Conical CAD/CAM Ti Blanks and Ti All Bases are to be sent to a BioHorizons validated milling center for manufacture.	TruBase S is a titanium component that is directly connected to endosseous dental implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. It is compatible with the following systems: • Zimmer TSV- 3.7, 4.1, 4.7, 6.0mm 3.5, 4.5, 5.7mm platform sizes) All digitally designed abutments and/or coping for use with the TruBase S are to be designed using Sirona inLab software or Sirona CEREC Software and manufacture using a Sirona CEREC or inLab MCX or MC XL milling unit.	The Dentsply Sirona Titanium Bases system is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. For AT EV 3.0 S, AT TX 3.0 S, BH 3.0 S, and SB L 3.3 L titanium bases, the indication is restricted to the replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system comprises three parts: Abutment Block material (CEREC Cercon 4D™ • Abutment Block) • Titanium Base (TiBase) • CAD/CAM system The TiBase is recommended for use with two-piece hybrid abutments and hybrid abutment crowns, used in conjunction with endosseous dental implants.
Product Code	NHA, PNP **(Identical Product Codes to predicate)**	NHA	NHA	NHA, PNP
Abutment Margin Diameter(s)	Engaging: 4mm , 4.5mm **(Identical Abutment Diameter(s) to primary predicate)**	Engaging: 4mm, 4.5mm	4.3mm, 5.3mm, 6.5mm	Unknown

Attributes	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device
Trade Name	**Conical CEREC Compatible Ti Bases**	**BioHorizons Tapered Pro Conical Implant System (TPC) (K240187)**	**TruBase S (K171532)**	**Dentsply Sirona Titanium Bases system (K250295)**
Ti-Base titanium component Height(s)	≥ 4 mm **(Identical Ti-Base titanium component Heights(s) to primary predicates)**	≥ 4 mm	4.7mm	≥ 4 mm
Ti-Base titanium component Gingival Height(s)	0.8mm, 2mm **(Identical Ti-Base titanium component Heights(s) to primary predicates)**	0.8mm, 2mm	0.8mm, 1.8mm, 2.8mm, and 3.8mm	1mm, 2mm, and 3mm
Material of Ti-Base titanium component	Ti-6Al-4V alloy **(Identical Material of the Ti-Base titanium component to primary predicate)**	Ti-6Al-4V alloy	Ti-6Al-4V ELI	Titanium alloy (Ti6Al4V)
Implant-to-Abutment Connection(s)	Conical, engaging **(Identical Implant-to-Abutment Connections(s) to primary predicate)**	Conical, engaging	Internal Hex	Internal Hex
Type of Retention	Screw-retained **(Identical Type of Retention to primary predicate)**	Screw-retained	Screw-retained	Unknown
Restorative Range of Angulation	Up to 20° **(Identical Restorative Range of Angulation to primary predicate)**	Up to 20°	Up to 20°	0 to 20°
Material of Superstructure	CEREC Cercon 4D™ (**K234018**) bonded using bonded using 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement (**K022476**) **(Identical Material of Superstructure to predicate(s))**	sagemax NexxZr zirconia (**K130991**) bonded using 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement (**K022476**) or similar	inCoris ZI meso (**K123664**)	CEREC Cercon 4D™ (**K234018**)
Patient-Specific Design	CAD/CAM manufactured superstructures **(Identical Patient-Specific Design to predicate)**	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures	CAD/CAM manufactured superstructures
Manufacturing Workflow	Sirona Dental CAD/CAM System Sirona CEREC®	Validated Milling Center	Sirona Dental CAD/CAM System	Design and manufacture of top half of abutment performed by clinician/lab in

Attributes	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device
Trade Name	**Conical CEREC Compatible Ti Bases**	**BioHorizons Tapered Pro Conical Implant System (TPC) (K240187)**	**TruBase S (K171532)**	**Dentsply Sirona Titanium Bases system (K250295)**
	workflow**(Identical Manufacturing workflow to predicate(s))**			CAD/CAM software system cleared in **K193408**. The CAD/CAM system incorporates the TiBases which allows for design of the top half of the abutment.
End-User Sterilization	Moist steam sterilization **(Identical Sterilization to predicate)**	Moist steam sterilization	Moist steam sterilization	Provided non-sterile (to be steam sterilized)
Shelf-Life	N/A **(Identical Shelf-Life to Primary Predicate)**	N/A	N/A	N/A
MRI Compatibility	MR Conditional **(Identical MRI Compatibility to Primary Predicate)**	MR Conditional	MR Conditional	MR Conditional
Biocompatibility	Biocompatible per ISO 10993-1 **(Identical Biocompatibility to Primary Predicate)**	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1