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

May 1, 2025

Re: K243521
Trade/Device Name: Conical Ti Base abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: January 31, 2025
Received: February 3, 2025

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243521

Device Name
Conical Ti Base abutments

Indications for Use *(Describe)*
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 Ti Base abutments are to be sent to a BioHorizons validated milling center for manufacture or to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

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 – K243521
BioHorizons Implant Systems Inc.
Conical Ti Base abutments
April 30, 2025

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	Jared Cooper, Ph.D., Sr. Director, Regulatory Affairs jcooper@biohorizons.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Conical Ti Base abutments
Common Names	Endosseous dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class 2
Product Code	NHA
Associated Product Code	PNP
Classification Panel	Dental
510(k) Submission Number	K243521
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

K240187, Tapered Pro Conical Implant System, BioHorizons Implant Systems Inc.

Secondary Predicate Device

K231307, Elos Accurate® Customized Abutment

INDICATIONS FOR USE STATEMENT

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 Ti Base abutments are to be sent to a BioHorizons validated milling center for manufacture or to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

SUBJECT DEVICE DESCRIPTION

The BioHorizons Conical Ti Base abutments are prosthetic components and are intended for the restoration of BioHorizons dental implants within the specific indications of each implant system. All Conical Ti Base abutments are two-piece titanium-base type abutments with a pre-manufactured titanium base component cemented to a zirconia superstructure to create the final finished dental abutment. All the titanium bases are manufactured from Ti-6Al-4V titanium alloy per *ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications* and are for single patient use. The prosthetics 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.

The Conical Ti-Base abutments are provided in engaging and non-engaging designs and are designed for single-unit or multi-unit restoration with a CAD/CAM zirconia superstructure attached to the abutment. The titanium base components are available for narrow and regular platforms and with gingival heights of 0.8 mm and 2.0 mm. The titanium base component post has been manufactured with matte finish creating a roughened surface to accommodate cementing. All patient-specific custom abutment fabrication for Conical Ti Base abutments are by prescription on the order of the clinician. All zirconia superstructures for use with the subject device Conical Ti Base abutments are made at a BioHorizons validated milling center under FDA quality system regulations, as cleared in ***K240187***, or according to a digital dentistry workflow (subject of this submission described in the section below). As cleared in ***K240187***, zirconia material, sagemax NexxZr® zirconia (K130991) is used to fabricate the patient-specific zirconia superstructure or direct crown. The cement for bonding of superstructures or crowns is a dual cure cement, 3M™ RelyX™ Unicem 2 Automix (K022476). These cleared materials are identical to the proposed digital dentistry workflow. The pre-manufactured titanium base component are not to be modified and are only intended to permit a customized zirconia restoration.

The design and fabrication of the zirconia superstructure will be conducted using a digital dentistry workflow requiring the use of the following equipment:

Scanner: 3Shape Trios 5 intra-oral scanner.
Design Software: 3Shape Abutment Designer Software, ***K151455***.
Zirconia Material: sagemax® NexxZr zirconia, ***K130991***.
CAM software: hyperDENT® Classic
Milling machine: imes-icore® CORiTEC 150i Pro milling machine
Cement: 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement, ***K022476***.

The designed superstructure is attached to the titanium base component by the use of an FDA-cleared cement, 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement, ***K022476***. The resulting final prosthetic restoration is screwed to the dental implant. All subject abutments are single-use and provided non-sterile. Final restoration (which includes the corresponding screw) is intended to be sterilized at the dental clinic before it is placed in the patient. The final abutment is equivalent to the final abutment cleared in ***K240187***.

MATERIAL COMPOSITION

There have been no changes to the subject devices since previous clearance, ***K240187***. All titanium subject device materials are Ti-6Al-4V per ASTM F136. The recommended zirconia superstructure materials are identical to the predicate materials in ***K240187***. These materials are FDA cleared and have a long history of use in dental applications and no new device materials are being introduced in the subject submission.

PERFORMANCE DATA

Non-clinical data including mechanical testing, biological safety, steam sterilization, and magnetic resonance testing relied upon information in the predicate submission since there were no changes since the previous clearance. New testing reviewed under this submission included supporting the CAD/CAM design and use within in a digital dentistry workflow and demonstrating controls of the digital dentistry workflow and that the final abutment is equivalent to the abutment produced by the validated milling center cleared in ***K240187***.

Additionally, surface characterization using scanning electron microscopy (SEM) and elemental analysis using energy-dispersive X-ray spectroscopy (EDX) was conducted on the titanium base component with a matte post. The surface analysis demonstrated that no residual blast media was detected on the surface of the titanium base component using a post-blast cleaning process. No clinical data were included in this submission. BioHorizons assessed the output of the proposed digital dentistry workflow including the CAD/CAM design of the zirconia superstructure and

determined the abutment angulation, diameter, height, wall thickness, tolerances, and part quality are equivalent to the validated milling center workflow cleared in ***K240187***.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in intended use, design, and technology to the primary predicate device and to the use within a digital dentistry workflow as the secondary predicate listed above. The substantial equivalence comparison table included below compares the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the secondary predicate devices.

Substantial Equivalence of Indication for Use Statement (IFUs)
The subject devices are similar in intended use to the primary predicate device cleared in ***K240187*** and adds indications for digital dentistry workflows from the secondary predicate, **K231307.**

Substantial Equivalence of Technological Characteristics
All subject devices are similar to or identical in design, materials and technological characteristics to corresponding abutments of the primary predicate device ***K240187***.

The titanium base components are provided non-sterile, packaging consists of 1073B Tyvek® and 48ga polyethylene terephthalate (PET)/2mil low density polyethylene (LDPE) pouches. This packaging is identical to that used for corresponding products cleared in ***K240187***.

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

- have the same intended use,
- use the same operating principles,
- incorporate the same basic designs,
- incorporate the same materials, and
- have the same packaging and are cleaned and sterilized using the same materials and processes.
- have the same use within a digital dentistry workflow

The basis that the subject device is substantially equivalent to the predicate devices is summarized in the following table.

Substantial Equivalence – Conical Ti Base abutments

Attributes	**Subject Device**	**Primary Predicate Device**	**Predicate Device**
Trade Name	**Conical Ti Base abutments**	**K240187- Tapered Pro Conical Implant System (Conical Ti Base abutments)**	**K231307- Elos Accurate Customized Abutment**
Reason for selection	Subject Device	Primary Predicate for Intended use, Design, technology, materials, manufacturing, packaging, and sterilization	Predicate for Digital Dentistry Workflow Indications and Directions for use
Indications for Use	BioHorizons conical dental prosthetic components connected to the endosseous dental implants	BioHorizons conical dental prosthetic components connected to the endosseous dental implants are	The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic

<table>
<tr><td></td><td>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 Ti Base abutments are to be sent to a BioHorizons validated milling center for manufacture or to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.
(Substantially equivalent to predicate)</td><td>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 Bases are to be sent to a BioHorizons validated milling center for manufacture.</td><td>restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.
The Elos Accurate® Customized Abutments are compatible with the implant systems listed in Table 1:

Table 1:
<table>
<tr><th>Platform Compatibility</th><th>Platform diameter [mm]</th><th>Implant Body diameter [mm]</th></tr>
<tr><td>Zimmer Screw-vent 3.5</td><td>Ø3.5</td><td>Ø3.7/Ø4.1</td></tr>
<tr><td>Zimmer Screw-vent 4.5</td><td>Ø4.5</td><td>Ø4.7</td></tr>
<tr><td>Zimmer Screw-vent 5.7</td><td>Ø5.7</td><td>Ø6.0</td></tr>
<tr><td>Biomet 3i Certain 3.4</td><td>Ø3.4</td><td>Ø3.25</td></tr>
<tr><td>Biomet 3i Certain 4.1</td><td>Ø4.1</td><td>Ø4</td></tr>
<tr><td>Biomet 3i Certain 5.0</td><td>Ø5</td><td>Ø5</td></tr>
<tr><td>Biomet 3i Certain 6.0</td><td>Ø6</td><td>Ø6</td></tr>
<tr><td>Straumann Standard RN</td><td>Ø4.8</td><td>Ø3.3/Ø4.1/Ø4.8</td></tr>
<tr><td>Straumann Standard WN</td><td>Ø6.5</td><td>Ø4.8</td></tr>
<tr><td>Neodent GM</td><td>Ø3.5/Ø4.5/Ø5.5/ Ø 6.5</td><td>Ø3.5/Ø3.75/Ø4/Ø4 .3/Ø 5/Ø 6/Ø7</td></tr>
<tr><td>Hiossen ET Mini</td><td>Ø3.2/Ø3.5</td><td>Ø3.2/Ø3.5</td></tr>
<tr><td>Hiossen ET Regular</td><td>Ø4/Ø4.5/Ø5/Ø5. 5/Ø6/Ø7</td><td>Ø4/Ø4.5/Ø5/ Ø5.5/Ø6/Ø7</td></tr>
</table>
All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments are either intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility or to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.</td></tr>
<tr><td>Stock Gingival Height, mm</td><td>0.8, 2.0
(Identical Stock Gingival Height to primary predicate)</td><td>0.8, 2.0</td><td>N/A</td></tr>
<tr><td>Angulation</td><td>up to 20°
(Identical Angulation to primary predicate)</td><td>up to 20°</td><td>Up to 30° maximum</td></tr>
<tr><td>Connection</td><td>Engaging, Non-engaging
(Identical Connection to primary predicate)</td><td>Engaging, Non-engaging</td><td>Engaging, Non-engaging</td></tr>
<tr><td>Material (titanium base component)</td><td>Ti-6Al-4V Alloy
(Identical Material to primary predicate)</td><td>Ti-6Al-4V Alloy</td><td>Ti-6Al-4V Alloy</td></tr>
<tr><td>Surface Treatment (Ti Base)</td><td>Anodized, Blast
(Similar Surface Treatment to primary predicate)</td><td>Anodized, None</td><td>N/A</td></tr>
<tr><td>Method of Manufacturing (Pre-manufactured Ti Base)</td><td>Traditional manufacturing methods (machine, clean, anodize (if applicable), Blast (engaging), package, label.
(Similar Method of Manufacturing to primary predicate)</td><td>Traditional manufacturing methods (machine, clean, anodize (if applicable), package, label.</td><td>N/A</td></tr>
<tr><td>Digital Design (Zirconia Superstructure)</td><td>3Shape Trios 5 intra-oral scanner, Design Software: 3Shape</td><td>Design Software: 3Shape Abutment Designer Software, K151455</td><td>3Shape scanner (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455</td></tr>
</table>

	Abutment Designer Software, ***K151455***		
Material (Zirconia Superstructure)	sagemax® NexxZr zirconia (K130991) bonded using 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement (K022476) or similar **(Identical Superstructure to primary predicate)**	sagemax® NexxZr zirconia (K130991) bonded using 3M™ RelyX™ Unicem 2 Automix Self-Adhesive Resin Cement (K022476) or similar	3M™ ESPE™ Lava™ Plus High Translucency Zirconia
Manufacturing (Zirconia Superstructure)	Digital Dentistry Workflow or Validated Milling Center	Validated Milling Center	Digital Dentistry Workflow or Validated Milling Center
Method of Manufacturing (Zirconia Superstructure)	imes-icore® CORiTEC 150i Pro milling machine **(Identical Method of Manufacturing to primary predicate)**	imes-icore® CORiTEC 150i Pro milling machine	CORiTEC milling unit (imes-icore)
Design Limitations	• 20° maximum post angulation. • 0.4mm minimum wall thickness. • 5mm maximum superstructure gingival margin height. Note: The maximum gingival margin height is inclusive of the gingival height of the stock titanium base component. A CAD library shall have a less-than-5mm maximum gingival margin height design limitation if measured in the software from the gingival height of the stock titanium base component. • Abutments with a superstructure post height less than 4.0mm are intended for multi-unit restorations only • Screw channel: • Engaging titanium base components: • 25° maximum angled screw channel for 0.8mm margin height • 15° maximum angled screw channel for 2.0mm margin height • Non-engaging titanium base components: straight screw channel only. **Note:** Minimal gingival margin height is established by the gingival height of the premanufactured titanium base component. The post-height of the abutment is measured above the total gingival margin height of the final patient-matched design. **(Similar Design Limitations to primary predicate)**	• 20° maximum post angulation. • 0.4mm minimum wall thickness. • 5mm maximum superstructure gingival margin height. • Abutments with a superstructure post height less than 4.0mm are intended for multi-unit restorations only • Screw channel: 25° maximum angled screw channel for 0.8mm margin height, 15° maximum angled screw channel for 2.0mm margin height. (Minimum gingival margin height is established by the gingival height of the stock Ti Base Abutment.) NOTE: The post-height of the abutment is measured above the total gingival margin height of the final patient-matched design	The Elos Accurate library file has built-in design limitations and the user isn't allowed to exceed these limitations. The material thickness should not be less than 0.5 mm (screw hole to outer surface). The gingival height should not exceed 5 mm. The maximum angulation should not exceed 20°. The post height should not be less than 4 mm for single unit restorations.
Usage	Single patient, Single use **(Identical Usage to primary predicate)**	Single patient, Single use	Single patient, Single use
Sterility	Non-Sterile, Steam sterilization **(Identical Sterility to primary predicate)**	Non-Sterile, Steam sterilization	Non-Sterile, Steam sterilization
Shelf-Life	N/A	N/A	N/A

	(Identical Shelf-Life to primary predicate)		
MRI Compatibility	MR Conditional **(Identical MRI Compatibility to primary predicate)**	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