March 16, 2021

BioHorizons Implant Systems, Inc.
℅ Floyd Larson
President
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K203252
Trade/Device Name: Multi-unit Abutments for CONELOG®
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 8, 2021
Received: February 9, 2021

Dear Floyd Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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 Steen
Assistant Director
DHT1B: Division of Dental 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)*
K203252

Device Name
Multi-unit Abutments for CONELOG®

Indications for Use *(Describe)*

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# 510(k) Summary

## Multi-unit Abutments for CONELOG®

**BioHorizons Implant Systems, Inc.**

March 3, 2021

ADMINISTRATIVE INFORMATION


| | |
|---|---|
| Manufacturer Name | BioHorizons Implant Systems, Inc.<br>2300 Riverchase Center<br>Birmingham, AL 35244<br>Telephone: +1 205-967-7887<br>Fax: +1 205-870-0304 |
| Official Contact | Bill Hornbuckle, Regulatory Affairs Associate, II |
| Representative/Consultant | Floyd G. Larson, MS, MBA<br>Kevin A. Thomas, PhD<br>PaxMed International, LLC<br>12264 El Camino Real, Suite 400<br>San Diego, CA 92130<br>Telephone: +1 858-792-1235<br>Fax: +1 858-792-1236<br>Email: flarson@paxmed.com<br>kthomas@paxmed.com |


DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Device Name | Multi-unit Abutments for CONELOG® |
| Common Name | Endosseous dental implant abutment |
| Regulation Number | 21 CFR 872.3630 |
| Regulation Name | Endosseous dental implant abutment |
| Regulatory Class | Class II |
| Product Code | NHA |
| Classification Panel | Dental |
| Reviewing Office | Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices) |
| Reviewing Division | Division of Health Technology 1 B (Dental Devices) |

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K191123, Multi-unit Abutments, Medentika GmbH

Additional Predicate Devices
K123491, Biodenta Dental Implant System – Multi-Use Abutment, Biodenta Swiss AG
K180998, BioHorizons CAD/CAM Bars, BioHorizons Implant Systems, Inc.
K113779, CONELOG® Implant System, Altatec GmbH

K193401, CAMLOG® / CONELOG® PROGRESSIVE-LINE Implants, Altatec GmbH
K172576, BioHorizons Tapered Short Implants, BioHorizons Implant Systems, Inc.
K103691, BioHorizons Abutments for Zimmer®, BioHorizons Implant Systems, Inc.

INDICATIONS FOR USE STATEMENT

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.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for BioHorizons Multi-unit Abutments for CONELOG® implants. The submission includes a set of multi-unit abutments and abutment screws compatible with two (2) implant lines within the CONELOG® Implant System, manufactured by Altatec GmbH. This compatibility was established via a business agreement between BioHorizons Implant Systems, Inc. and Altatec GmbH. The corresponding compatible CONELOG implant platform diameters range from 3.3 mm to 4.3 mm. All sizes of the compatible CONELOG dental implants have the same tapered implant/abutment interface connection design as the subject device. The connection includes three (3) positioning cams on the abutment that engage complementary features on the implant to prevent rotation of the abutment relative to the implant.

The subject device Multi-unit Abutments for CONELOG are designed for attachment of single-unit and multi-unit screw-retained restorations. They are available in straight and angled designs, which are referred to as Multi-unit Straight Abutment for CONELOG and Multi-unit Angled Abutment for CONELOG, respectively. The straight and angled designs each are available in gingival heights of 2, 3, and 4 mm. All designs have a prosthetic diameter of 4.8 mm.

Multi-unit Angled Abutment for CONELOG designs have the coronal end inclined at either 17° or 30° to the implant axis for correction of angulation. The angled abutment includes an internal thread in the coronal portion of the abutment to accommodate a prosthetic screw for the screw-retained restoration. Each angled abutment is available in Type A or Type B orientations. Type A refers to an orientation in which one (1) of the three (3) positioning cams is aligned opposite the direction of abutment angulation. Type B refers to an orientation in which the cam alignment coincides with the direction of abutment angulation.

The subject device Multi-unit Abutments for CONELOG includes Class II abutment-level prosthetic components used for fabrication of provisional and final restorations. These prosthetic components include copings made of titanium alloy, gold alloy, or polyoxymethylene, a temporary cover cap made of titanium alloy, and prosthetic screws made of titanium alloy. The titanium alloy and gold copings and the prosthetic screws become part of the finished restoration.

All subject device abutments and abutment screws are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: sterilization validation according to ANSI/AAMI/ISO 11137-1 and ANSI/AAMI/ISO 11137-2, referenced from K172576, and K103691; biocompatibility according to ISO 10993-5 and ISO 10993-12, referenced from K103691, K172576 and K193401; and static compression and compression fatigue testing according to ISO 14801. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the additional predicate devices listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and additional predicate devices.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate K191123. Slight differences in the language of the subject device and primary predicate device IFUS do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function.

Minor differences between the IFUS for the subject device and the primary predicate include the exact wording regarding single-unit restorations (not applicable to the primary predicate K191123), specific device names, and compatible implant lines. Minor differences between the subject device IFUS and that of the additional predicate devices are related to the specific device names, design features, requirement for the use of validated milling centers, and use of the devices.

None of these minor differences impact safety or effectiveness because all IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

The subject device abutment designs are substantially equivalent to the abutment designs of the primary predicate K191123. The subject device and primary predicate K191123 both include straight and angled multi-unit abutment designs. The ranges of dimensions of platform diameter and gingival height for the subject device abutments are within the corresponding ranges of the primary predicate K191123. The subject device abutments and the primary predicate K191123 abutments also are substantially equivalent in terms of prosthesis attachment (screw-retained), restorations (multi-unit), abutment-implant interface (internal connection, engaging design), abutment angle (0°, 17°, 30°), material (titanium alloy), and sterilization (gamma irradiation). The subject device prosthetic components (copings and prosthetic screws) are similar in design and materials to the Multi-unit Caps and associated prosthetic screws of the primary predicate device.

The additional predicate device K123491 is for support of substantial equivalence of single-unit restorations. Both the subject device multi-unit abutment designs and the additional predicate device K123491 multi-unit abutment designs are substantially equivalent in terms of restoration options (single-unit, multi-unit).

The subject device abutments have interface connections and implant/abutment platforms that are identical to those of the compatible CONELOG dental implants cleared in the additional predicate devices K113779 and K193401. The subject device includes designs for compatible CONELOG implant platforms of 3.3 mm and 3.8/4.3 mm.

The additional predicate device K180998 is for support of substantial equivalence of compatible BioHorizons interface connections. The CAD/CAM abutment-level bar designs in K180998 are compatible with the subject device abutments.

The subject device abutments and abutment screws are manufactured from titanium alloy conforming to ASTM F136, using the identical material and processing used for titanium alloy components cleared in the predicate devices K180998 and K172576.

Mechanical performance testing of the subject device was performed according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*. The fatigue limit data demonstrated that constructs of the subject device abutments in combination with the previously-cleared compatible implants, and used according to the proposed labeling, have sufficient strength for their intended use.

Minor differences in the designs, dimensions, sizes, or compatible implant lines among the subject device, the primary predicate device, and the additional predicate devices do not affect substantial equivalence. These minor differences do not impact safety or effectiveness because these differences are related to the compatible implant designs or are mitigated by the mechanical performance testing.

CONCLUSION

The subject device, the primary predicate device and the additional predicate devices have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device, the primary predicate device, and the additional predicate devices encompass the same range of physical dimensions, are packaged in similar materials, and are to be sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

## Table of Substantial Equivalence – Indications for Use Statement

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td colspan="2">Subject Device</td></tr>
<tr><td>Multi-unit Abutments for CONELOG®<br>BioHorizons Implant Systems, Inc.</td><td>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. The</td></tr>
<tr><td colspan="2">Primary Predicate Device</td></tr>
<tr><td>K191123<br>Multi-unit Abutments<br>Medentika GmbH</td><td>Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.<br><br>Multi-unit Abutments are used for the restoration of the following dental implant systems:
<table>
<tr><th>Medentika series</th><th>Implant system</th><th>Implant diameter</th><th>Platform diameter</th></tr>
<tr><td>EV-Series</td><td>Dentsply® Implants - ASTRA TECH OsseoSpeed®</td><td>3.6, 4.2, 4.8</td><td>3.6, 4.2, 4.8</td></tr>
<tr><td>F-Series</td><td>Nobel Biocare NobelActive - NobelReplace</td><td>3.5, 4.3, 5.0</td><td>NP 3.5, RP 4.3/5.0</td></tr>
<tr><td>H-Series</td><td>Biomet 3i - Certain</td><td>3.25, 4.0</td><td>3.4, 4.1</td></tr>
<tr><td>L-Series</td><td>Straumann - Bone Level</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>N-Series</td><td>Straumann - Soft Tissue Level</td><td>4.1, 4.8</td><td>4.8, 6.5</td></tr>
<tr><td>R-Series</td><td>Zimmer Dental Tapered Screw-vent</td><td>3.3, 3.7, 4.1, 4.7</td><td>3.5, 4.5</td></tr>
</table></td></tr>
<tr><td colspan="2">Additional Predicate Devices</td></tr>
<tr><td>K123491<br>Biodenta Dental Implant System – Multi-Use Abutment<br>Biodenta Swiss AG</td><td>Biodenta Dental Implant System Multi-Use Abutments are intended for terminal or intermediate abutment support for fixed or removable crown, bridgework and to retain overdentures.</td></tr>
<tr><td>K180998<br>BioHorizons CAD/CAM Bars<br>BioHorizons Implant Systems, Inc.</td><td>BioHorizons CAD/CAM Bars are intended for use as superstructures of a multiple-unit endosseous dental implant system, attaching directly to implants or abutments, to support a prosthetic device in a partially or fully edentulous patient for the purpose of restoring chewing function. Implant-level bars are compatible with all BioHorizons Internal and Tapered Internal implant systems. Implant-level bars are compatible with Zimmer Dental Screw-Vent® and Tapered Screw Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex connection mating platform diameters and are intended to be used with straight bar cylinders only. Abutment-level bars are compatible with BioHorizons Multi-unit Abutments.<br><br>All digitally designed BioHorizons CAD/CAM Bars are intended to be sent to a BioHorizons-validated milling center for manufacture.</td></tr>
</table>

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| K113779<br>CONELOG® Implant System<br>Altatec GmbH | CONELOG® Implant System Implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. CONELOG® Implant System Abutments are intended for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.<br>CONELOG® Implants with 3.3 mm diameter have the following additional specific indications: These are in alternative in cases where the alveolar ridge width is only 5 – 6 mm. Because of their lower mechanical strength compared with larger diameter implants, they should only be used under the following conditions:<br>- As single implants, they should be used only to replace mandibular incisors and/or maxillary lateral incisors.<br>- An edentulous arch can only be restored with a bar retained superstructure with at least four implants of 3.3 mm diameter without distal extensions.<br>- Implants of Ø 3.3 are suitable for a partially edentulous arch when combined with implants of larger diameter for splinted superstructures. However, the limited strength of the implants with Ø 3.3 mm must be taken into account.<br>- Avoid excessive mechanical stressing of the implants when using ball abutments in combination with Ø 3.3 mm implants.<br>- The healing time for Ø 3.3 mm implants is at least 12 weeks.<br>CONELOG® Implants with 7 mm length have the following additional specific indications:<br>CONELOG® SCREW-LINE Implants should only be used when there is not enough space for a longer implant. Delayed loading in single tooth replacement is indicated with these implants. If the ratio of crown length to implant length is unfavorable the biomechanical risk factors have to be considered and appropriate measures have to be taken by the dental professional. |

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| K193401<br>CAMLOG® / CONELOG® PROGRESSIVE-LINE Implants<br>Altatec GmbH | CAMLOG®/CONELOG® PROGRESSIVE-LINE implants are intended for the restoration of edentulous and partially edentulous jaws with prosthetic restorations such as implant-supported single crowns, bridges and full dentures.<br>Specifically for:<br>- single-tooth gaps,<br>- partially edentulous jaws with several missing teeth or<br>- edentulous jaws<br>CAMLOG®/CONELOG® PROGRESSIVE-LINE implants are suitable for oral endosseous implantation in the maxillary and/or mandibular bone and are intended for immediate or delayed implantation. They are indicated for transgingival healing (one-stage, using healing caps or abutments) or subgingival healing (two-stage, using cover screws). If a single-phase healing is intended, the implants can be loaded immediately if the primary stability achieved is adequate for functional loading. In conjunction with the corresponding abutments, the implants can be used for screw-retained or cemented restorations such as single crowns, bridges and full dentures.<br>CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants with a diameter of 3.3 mm have the following additional specific indications:<br>Implants with a diameter of 3.3 mm are indicated as an alternative in cases where the alveolar ridge width is only 5–6 mm. Because of their lower tensile strength compared with larger diameter implants, they should only be used under the following conditions:<br>- As single implants, they should be used only to replace mandibular incisors and/or maxillary lateral incisors.<br>- An edentulous arch can only be restored with a bar retained superstructure with at least four implants of 3.3 mm diameter without distal extensions.<br>- Implants of Ø 3.3 are suitable for a partially edentulous arch when combined with implants of larger diameter for splinted superstructures. However, the limited strength of the implants with Ø 3.3 mm must be taken into account.<br>- Avoid excessive mechanical stressing of the implants when using ball abutments in combination with Ø 3.3 mm implants.<br>- The healing time for diameter 3.3 mm implants is at least 12 weeks.<br>CONELOG® Implants with 7 mm length have the following additional specific indications:<br>These implants should only be used when there is not enough space for a longer implant. Delayed loading in single tooth replacement is indicated with these implants. If the ratio of crown length to implant length is unfavorable the biomechanical risk factors have to be considered and appropriate measures have to be taken by the dental professional. |
| K172576<br>BioHorizons Tapered Short Implants<br>BioHorizons Implant Systems, Inc. | 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. |
| K103691<br>BioHorizons Abutments for Zimmer®<br>BioHorizons Implant Systems, Inc. | 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.<br><br>BioHorizons Titanium Base Abutments and Laser-Lok Titanium Base Abutments are intended to be used as straight abutments. |

Table of Substantial Equivalence – Technological Characteristics

| Comparison | Subject Device | Primary Predicate Device | Additional Predicate Device | Additional Predicate Device | Additional Predicate Device | Additional Predicate Device | Additional Predicate Device | Additional Predicate Device |
|---|---|---|---|---|---|---|---|---|
| | Multi-unit Abutments for CONELOG®<br><br>BioHorizons Implant Systems, Inc. | K191123<br>Multi-unit Abutments<br><br>Medentika GmbH | K123491<br>Biodenta Dental Implant System – Multi-Use Abutment<br><br>Biodenta Swiss AG | K180998<br>BioHorizons CAD/CAM Bars<br><br>BioHorizons Implant Systems, Inc. | K113779<br>CONELOG® Implant System<br><br>Altatec GmbH | K193401<br>CAMLOG®/ CONELOG® PROGRESSIVE-LINE Implants<br><br>Altatec GmbH | K172576<br>BioHorizons Tapered Short Implants<br><br>BioHorizons Implant Systems, Inc. | K103691<br>BioHorizons Abutments for Zimmer®<br><br>BioHorizons Implant Systems, Inc. |
| Product Code(s) | NHA | NHA | NHA | NHA | DZE, NHA | DZE | DZE | NHA |
| **Design** | | | | | | | | |
| Abutment Design | Multi-unit Straight Abutment<br>Multi-unit Angled Abutment | Straight Multi-unit Abutment<br>Angled Multi-unit Abutment | Straight Multi-Use Abutment<br>Angled Multi-Use Abutment | CAD/CAM Abutment-level Bars | Various designs | NA<br>(Abutments cleared previously) | NA<br>(Abutments cleared previously) | Various designs |
| Prosthesis Attachment | Screw-retained | Screw-retained | Screw-retained | Screw-retained | Cement-retained, Screw-retained | Cement-retained, Screw-retained | Cement-retained, Screw-retained | Cement-retained, Screw-retained |
| Restoration | Single-unit, Multi-unit | Multi-unit | Single-unit, Multi-unit | Multi-unit | Single-unit, Multi-unit | Single-unit, Multi-unit | Single-unit, Multi-unit | Single-unit, Multi-unit |
| Abutment/ Implant Platform Diameter (mm) | 3.3 – 4.3 | 3.3 – 6.5 | 3.5 – 4.8 | NA | 3.3 – 4.3 | 3.3 – 5.0 | 3.5, 4.5 | 3.5, 4.5, 5.7 |
| Gingival height (mm) | 2 – 4 | 0.6 – 5 | 2 – 5 | NA | 1.0 – 4.5 | NA<br>(No abutments included) | NA<br>(No abutments included) | 1.4 – 6.0 |
| Abutment Angle | Straight (0°), 17°, 30° | Straight (0°), 17°, 30° | Straight (0°), 18°, 30° | NA | Straight (0°), 15°, 20°, 30° | NA<br>(No abutments included) | NA<br>(No abutments included) | Straight (0°), Angled (15° min; 25° max) |
| Abutment/ Implant Interface | Internal, Engaging | Internal, Engaging and Non-engaging | Internal, Engaging and Non-engaging | NA | Internal, Engaging | Internal, Engaging | Internal, Engaging | Internal, Engaging |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Abutment Materials | Titanium alloy, ASTM F136 | Titanium alloy, ASTM F136 | Titanium alloy, ASTM F136 | Titanium alloy, ASTM F136 | Titanium alloy, ASTM F136 | NA (No abutments included) | NA (No abutments included) | Titanium alloy, ASTM F136; Zirconia ceramic, ISO 13356; Gold alloy 6019; PEEK, ASTM F2026 |
| Abutment Screw Materials | Titanium alloy, ASTM F136 | Titanium alloy, ASTM F136 | Titanium alloy, ASTM F136 | Titanium alloy, ASTM F136 | Titanium alloy, ASTM F136 | NA (No abutments included) | NA (No abutments included) | Titanium alloy, ASTM F136 |
| Prosthetic Components Included | Copings, prosthetic screws, temporary cap | Copings, prosthetic screws | Not described in 510(k) Summary | N/A | N/A | N/A | NA | NA |
| Coping Materials | Titanium alloy, Gold | Titanium, Gold, Cobalt Chromium | Not described in 510(k) Summary | N/A | N/A | N/A | N/A | N/A |
| **How Provided** | | | | | | | | |
| Abutments | Sterile by gamma irradiation | Sterile by gamma irradiation | Non-sterile | Non-sterile | Sterile by gamma irradiation | NA (No abutments included) | NA (No abutments included) | Sterile by gamma irradiation |
| Abutment Screws | Sterile by gamma irradiation | Sterile by gamma irradiation | Non-sterile | Non-sterile | Sterile by gamma irradiation | NA (No abutments included) | NA (No abutments included) | Sterile by gamma irradiation |
| Usage | Single patient, single use | Single patient, single use | Single patient, single use | Single patient, single use | Single patient, single use | NA (No abutments included) | NA (No abutments included) | Single patient, single use |