September 24, 2021

Talladium España, SL
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K212108
Trade/Device Name: Dynamic TiBase
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 2, 2021
Received: July 6, 2021

Dear Kevin Thomas:

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,

for Andrew 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)*

K212108

Device Name

Dynamic TiBase

Indications for Use *(Describe)*

Dynamic TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

| Implant Compatibility | Implant Body Diameter, mm | Implant Platform, mm |
|---|---|---|
| SPI® CONTACT Dental Implant | 2.7 | 3.5 |
| | 3.5 | 4.0 |
| | 3.5 | 4.5 |
| | 4.2 | 5.0 |

All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Thommen Medical validated milling center for manufacture.

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.**

# 510(k) Summary
# K212108
# Talladium España, SL
# Dynamic TiBase

September 23, 2021

## ADMINISTRATIVE INFORMATION


| | |
|---|---|
| Manufacturer Name | Talladium España, SL<br>C/ Virginia Woolf, 17<br>Lleida, Lleida, ES 25005<br>Telephone +34 973-289-580 |
| Official Contact | Xavier Soca Filella, General Manager |
| Representative/Consultant | Kevin A. Thomas, PhD<br>Floyd G. Larson, MS, MBA<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 kthomas@paxmed.com<br>flarson@paxmed.com |


## DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Proprietary Name | Dynamic TiBase |
| 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 |
| 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
K202026, Blue Sky Bio CAD-CAM Abutments, Blue Sky Bio, LLC

Reference Devices
K182246, MIST IC, Imagine Milling Technologies, LLC
K034014, SPI® CONTACT Dental Implant, Thommen Medical AG
K072933, SPI® CONTACT Platform Ø 4.0 mm, Thommen Medical AG
K191919, Elos Accurate® Hybrid Base, Elos Medtech Pinol A/S
K162021, 3.0 Dynamic TiBase, Talladium España, SL

INDICATIONS FOR USE STATEMENT

Dynamic TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

| Implant Compatibility | Implant Body Diameter, mm | Implant Platform, mm |
|---|---|---|
| SPI® CONTACT Dental Implant | 2.7 | 3.5 |
| | 3.5 | 4.0 |
| | 3.5 | 4.5 |
| | 4.2 | 5.0 |

All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Thommen Medical validated milling center for manufacture.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for Dynamic TiBase, a series of two-piece titanium base abutments that require the fabrication of patient-specific custom superstructures using CAD-CAM technology. In final, finished form, the subject device abutments are intended to be used as a two-piece abutment composed of the base bottom-half (titanium base) with a bonded CAD-CAM zirconia top-half. Each patient-specific zirconia superstructure is individually prescribed by the clinician and manufactured by an authorized milling center.

The subject device abutments are compatible with SPI® CONTACT dental implant fixtures manufactured by Thommen Medical AG, and cleared in K034014 and K072933, in the following sizes:

- 2.7 mm body diameter/3.5 mm platform;
- 3.5 mm body diameter/4.0 mm platform;
- 3.5 mm body diameter/4.5 mm platform; and
- 4.2 mm body diameter/5.0 mm platform.

The compatibility between the subject device and the Thommen SPI® CONTACT dental implant fixtures was established by a business agreement between Talladium España, SL and Thommen Medical AG.

All subject device abutments and abutment screws are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136 and ISO 5832-3.

All Dynamic TiBase abutments are provided in a straight design (no angulation in the TiBase portion), and with implant connections for crowns (engaging) or bridges (non-engaging). All Dynamic TiBase abutments are provided with a gingival height of 0.7 mm; additional gingival height may be provided in the zirconia superstructure as described below. All Dynamic TiBase abutments are provided with a cut-out in the prosthetic post to accommodate a restoration with an angled screw channel when clinically necessary. The prosthetic post heights are 4.0 mm (maximum height) / 2.3 mm (cutout height), and 9.0 mm/3.5 mm. Dynamic TiBase abutments with a 9.0 mm post height may be shortened to no less than 4 mm for a single-unit restoration.

All zirconia copings (superstructures) for use with the subject device Dynamic TiBase will be made at a Thommen Medical validated milling center under FDA quality system regulations, and the material will conform to ISO 13356.

The design parameters for the CAD-CAM zirconia superstructure for Dynamic TiBases are:

Minimum wall thickness – 0.43 mm
Minimum post height for single-unit restorations – 4.0 mm
Maximum gingival height – 5.83 mm
Minimum gingival height – 0.7 mm (in the TiBase, not the zirconia superstructure)
Maximum angulation – 30°

The recommended cement for bonding the zirconia superstructure to the Dynamic TiBases to create the final two-piece abutment is G-CEM LinkAce™ cleared in K120243.

## PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included: biocompatibility testing according to ISO 10993-5 and ISO 10993-12; moist heat sterilization validation according to ISO 17665-1 and ISO 11737-2; and static compression and compression fatigue testing according to ISO 14801 of worst-case constructs comprising the subject device abutments, zirconia superstructures made to the limits listed above, subject device abutment screws, and compatible Thommen SPI® CONTACT dental implant fixtures. 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 reference devices listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and reference devices.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate device K202026 and the reference devices K182246, K191919, and K162021; differences in language of the Indications for Use statements do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function.

The minor differences among the IFUS for the subject device, the primary predicate K202026, and the reference devices K182246, K191919, and K162021 include differences in the specific wording regarding compatible dental implants, and differences in the specific wording regarding the required validated milling centers. K162021 is indicated only for multi-unit prostheses. Similarities among the IFUS for the subject device, the primary predicate K202026, and the reference devices K182246, K191919, and K162021 include wording regarding single-unit and multi-unit restorations (K162021 is indicated only for multi-unit) and the requirement for use of validated milling centers.

The reference devices K072933 and K034014 are for substantial equivalence of the identical Thommen Medical AG SPI® CONTACT implant interface connections and platforms. Differences among the IFUS for the subject device and these reference devices are wording regarding the implant components included

in K072933 and K034014; the relevant similarities include wording concerning prosthetic support of single-unit and multi-unit restorations.

The reference device K191919 is for support of substantial equivalence of the performance testing data. Similarities between the IFUS for the subject device and K191919 include wording on the intended use for single-unit and multi-unit restorations and the requirement for use of validated milling centers. Minor differences between the IFUS for the subject device and K191919 include specific wording about base abutments and the listing of compatible implant systems. None of these minor differences impact substantial equivalence because all IFUS express an equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

The reference device K162021 is for identical manufacturing and technological characteristics for the proposed titanium alloy abutments and abutment screws, including the anodization process that is identical to that used for the subject devices.

The subject device abutments have interface connections and platforms that are identical to the compatible Thommen Medical AG SPI® CONTACT implant interface connections and platforms cleared in K072933 and K034014. The subject device includes designs for compatible Thommen Medical AG SPI® CONTACT implant platforms ranging from 3.5 mm to 5.0 mm.

The subject device abutments are substantially equivalent in material and design to the corresponding abutments in the primary predicate device K202026. The final finished device for both the subject device abutments and the titanium base abutments cleared in K202026 is intended to be used as a two-piece abutment composed of the base bottom-half (titanium base) bonded to a CAD-CAM zirconia top-half.

The subject device abutments are provided with abutment-implant platform diameters and prosthetic platform diameters that are substantially equivalent to those of the corresponding abutments in K202026. Differences in the zirconia superstructure design parameters between the subject device and the primary predicate device K202026 include slight differences in the minimum wall thickness and gingival height; these differences are mitigated by the mechanical testing described below.

The reference device K182246 is for support of substantial equivalence of the subject device prosthetic post design, which has a cut-out to allow a screwdriver to access the abutment screw at an angle (if necessary) to tighten the screw and secure the abutment to the implant fixture. The MIST IC S-LINK abutment cleared in K182246 is a titanium base abutment manufactured from titanium alloy to be used with a CAD-CAM zirconia superstructure intended for cement-retained, single-unit or multi-unit restorations. Prior to bonding of the zirconia superstructure, MIST IC S-LINK has a post height of 3.8 mm with a cut-down channel to allow a screwdriver to access the abutment screw at an angle (if necessary) to tighten the screw. The subject device abutments have a prosthetic post with a similar cut-down channel with a minimum post height of 4 mm prior to bonding of the zirconia superstructure.

Minor differences in the design parameters for zirconia copings to be used with the subject device base abutments and for zirconia copings to be used with the predicate device base abutments (minimum wall thickness, maximum gingival height, maximum angulation) are mitigated by mechanical testing of the subject device performed in conformance with ISO 14801.

The subject device includes abutments made of titanium alloy conforming to ASTM F136 and ISO 5832-3. The titanium alloy subject device components are manufactured from identical materials, in the identical facilities using the identical manufacturing processes as used for Talladium España, SL products cleared previously in the reference device K162021. In addition, subject device titanium alloy abutments and abutment screws are anodized using a process that is identical to the anodization process used for Talladium España, SL products cleared previously in the reference device K162021. The subject device abutments are to be used with superstructures fabricated from zirconia conforming to ISO 13356; this is the same material used for superstructures in the primary predicate device K202026 and in the reference devices K182246 and K191919. Confirmatory biocompatibility testing for finished subject devices made from titanium alloy with cemented zirconia superstructures was performed according to ISO 10993-5 and ISO 10993-12.

Mechanical performance testing of the subject device was performed in conformance to ISO 14801. The fatigue limit data demonstrated that constructs of the subject device abutments fabricated to the limits stated in the proposed labeling, in combination with previously-cleared compatible Thommen Medical AG SPI® CONTACT implants, have sufficient strength for their intended use.

All subject device abutments and all abutments cleared in K202026, K182246, and K191919 are provided non-sterile and are to be moist heat sterilized by the end user.

Minor differences in the designs, dimensions, sizes, or compatible implant lines among the subject device, the primary predicate device, and the reference 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 and are mitigated by the mechanical performance testing.

## CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, have similar technological characteristics, and are made of identical or similar materials. The subject device, the primary predicate, and the reference devices encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate device listed above.

## Table of Substantial Equivalence – Indications for Use Statements

<table>
<tr><th></th><th>Indications for Use Statements</th></tr>
<tr><td>Subject Device<br>K212108<br>Dynamic TiBase<br>Talladium España, SL</td><td>Dynamic TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.<br><br>
<table>
<tr><th>Implant Compatibility</th><th>Implant Body Diameter, mm</th><th>Implant Platform, mm</th></tr>
<tr><td rowspan="4">SPI® CONTACT Dental Implant</td><td>2.7</td><td>3.5</td></tr>
<tr><td>3.5</td><td>4.0</td></tr>
<tr><td>3.5</td><td>4.5</td></tr>
<tr><td>4.2</td><td>5.0</td></tr>
</table>
<br>All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Thommen Medical validated milling center for manufacture.</td></tr>
<tr><td>Primary Predicate Device</td><td></td></tr>
<tr><td>K202026<br>Blue Sky Bio CAD-CAM Abutments<br>Blue Sky Bio, LLC</td><td>Blue Sky Bio CAD-CAM Abutments are intended to be used in conjunction with Blue Sky Bio endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.<br><br>All digitally designed abutments for use with Blue Sky Bio CAD-CAM Abutments are intended to be sent to a Blue Sky Bio validated milling center for manufacture.</td></tr>
<tr><td>Reference Devices</td><td></td></tr>
<tr><td>K182246<br>MIST IC<br>Imagine Milling Technologies, LLC</td><td>MIST IC abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. They are intended to support a single-unit or multi-unit, cement-retained prosthesis in the mandible or maxilla. MIST IC abutments are compatible for use with the following implants:<br><br>
<table>
<tr><th>Keystone Dental Implant Line</th><th>Platform Diameter (mm)</th><th>Body Diameter (mm)</th></tr>
<tr><td>Genesis</td><td>3.8, 4.5, 5.5, 6.5</td><td>3.8, 4.5, 5.5, 6.5</td></tr>
<tr><td>PrimaConnex® 1.0 (Straight)</td><td>3.5, 4.1, 5.0</td><td>3.3, 4.0, 5.0</td></tr>
<tr><td>PrimaConnex® 1.0 (Tapered)</td><td>3.5, 4.1, 5.0</td><td>3.5, 4.1, 5.0</td></tr>
</table>
<br>All digitally designed custom abutments for use with MIST IC abutments are to be sent to an Imagine Milling Technologies validated milling center for manufacture.</td></tr>
<tr><td>K072933<br>SPI® CONTACT Platform Ø 4.0 mm<br>Thommen Medical AG</td><td>SPI® CONTACT Platform 0 4.0 mm is intended to be surgically placed, either immediately after extraction or following healing, in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. SPI® Dental Implants can be loaded immediately if they are splinted with a bar on four implants in the mandibular arch or six implants in the maxillary arch.</td></tr>
<tr><td>K034014<br>SPI® CONTACT Dental Implant<br>Thommen Medical AG</td><td>The Thommen SPI® CONTACT Dental Implant is intended to be surgically placed, either immediately or delayed, in the bone of the maxillary or mandibular arch to provide support for crowns, bridges or overdentures. SPI® CONTACT implants can be loaded immediately if they are splinted with a bar on four implants in the mandibular arch or six implants in the maxillary arch .<br><br>Contraindications for the use of SPI® CONT ACT implants 0 3.5 mm:<br>These implants are not suitable for applications in areas where pronounced rotation and translation movements occur, causing the implant to be subjected to large bending moments.<br>- Restoration of posterior teeth in the upper or lower jaw<br>- Single-tooth restoration of canines and central incisors in the upper jaw<br>- Any application involving retentive anchors.</td></tr>
</table>

## Table of Substantial Equivalence – Indications for Use Statements

<table>
<tr><th></th><th>Indications for Use Statements</th></tr>
<tr><td>K191919<br>Elos Accurate® Hybrid Base<br>Elos Medtech Pinol A/S</td><td>The Elos Accurate® Hybrid Base™ is intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations.<br>The Hybrid Base™ is used as an interface between a dental implant and a zirconia superstructure and will be attached to the implant using the included prosthetic screw and attached to the zirconia superstructure by cementing.<br>The Elos Accurate® Hybrid Base™ is compatible with the implant systems listed in Table 1.<br><br>Table 1.<br><table><tr><th>Implant Platform compatibility</th><th>Platform diameter [mm]</th><th>Implant Body diameter [mm]</th></tr><tr><td>Nobel Replace NP</td><td>3.5</td><td>3.5</td></tr><tr><td>Nobel Replace RP</td><td>4.3</td><td>4.3</td></tr><tr><td>Nobel Replace WP</td><td>5</td><td>5</td></tr><tr><td>Nobel Replace 6.0</td><td>6</td><td>6</td></tr><tr><td>Nobel CC 3.0</td><td>3</td><td>3</td></tr><tr><td>Nobel CC NP</td><td>3.5</td><td>3.5 & 3.75</td></tr><tr><td>Nobel CC RP</td><td>3.9</td><td>4.3 & 5</td></tr><tr><td>Nobel CC WP</td><td>5.1</td><td>5.5</td></tr><tr><td>Straumann Bone Level NC</td><td>3.3</td><td>3.3</td></tr><tr><td>Straumann Bone Level RC</td><td>4.1 & 4.8</td><td>4.1 & 4.8</td></tr><tr><td>Astra Tech 3.0</td><td>3</td><td>3</td></tr><tr><td>Astra Tech 3.5/4.0</td><td>3.5 & 4</td><td>3.5 & 4</td></tr><tr><td>Astra Tech 4.5/5.0</td><td>4.5 & 5</td><td>4.5 & 5</td></tr><tr><td>Astra Tech EV 3.0</td><td>3</td><td>3</td></tr><tr><td>Astra Tech EV 3.6</td><td>3.6</td><td>3.6</td></tr><tr><td>Astra Tech EV 4.2</td><td>4.2</td><td>3.6 & 4.2</td></tr><tr><td>Astra Tech EV 4.8</td><td>4.8</td><td>4.2 & 4.8</td></tr><tr><td>Astra Tech EV 5.4</td><td>5.4</td><td>5.4</td></tr></table><br>All digitally designed zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are only intended to be sent and manufactured at an FDA registered Elos Medtech approved milling facility.</td></tr>
<tr><td>K162021<br>3.0 Dynamic TiBase<br>Talladium España, SL</td><td>3.0 Dynamic TiBase are intended for use with dental implants as a support for multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.<br>Compatibility of 3.0 Dynamic TiBase®:<br><br><table><tr><th>Implant Compatibility</th><th>Dynamic TiBase® reference</th><th>Trade Name</th><th>Implant Diameter (mm)</th><th>Abutment Post Height (mm)</th><th>Retention Type<br>Single unit = Engaging<br>Multi-Unit = Non-Engaging</th><th>Screw Type</th><th>Angulation</th><th>Abutment Connection</th></tr><tr><td>DIO®</td><td>IND3OTSHRP/TiA</td><td>UF</td><td>4.0</td><td>4.0</td><td>Multi-unit</td><td>Dynamic Screw</td><td>0° to 30°</td><td>INTERNAL HEXAGON</td></tr><tr><td>OSSTEM®</td><td>IND3OTSRNP/TiA</td><td>TS NARROW PLATFORM</td><td>3.5</td><td>3.8</td><td>Multi-unit</td><td>Dynamic Screw</td><td>0° to 20°</td><td>INTERNAL HEXAGON</td></tr></table><br>All Ti-base abutments, including the designed zirconia superstructure, are intended to be manufactured and finalized by Talladium Espana.</td></tr>
</table>

## Table of Substantial Equivalence – Technological Characteristics

| Comparison | Subject Device | Primary Predicate Device | Reference Device | Reference Device | Reference Device | Reference Device |
|---|---|---|---|---|---|---|
| | **K212108<br>Dynamic TiBase<br><br>Talladium España, SL** | **K202026<br>Blue Sky Bio CAD-CAM Abutments<br>Blue Sky Bio, LLC** | **K182246<br>MIST IC<br><br>Imagine Milling Technologies, LLC** | **K072933<br>SPI® CONTACT Platform Ø 4.0 mm<br>Thommen Medical AG** | **K034014<br>SPI® CONTACT Dental Implant<br><br>Thommen Medical AG** | **K191919<br>Elos Accurate® Hybrid Base<br><br>Elos Medtech Pinol A/S** |
| **Reason for Predicate Device / Reference Device** | **Not applicable** | **Indications for Use Statement<br>Abutment designs** | **Prosthetic post design, with angled screw channel feature** | **Compatible identical implant interface and platforms** | **Compatible identical implant interface and platforms** | **Performance testing data** |
| **Product Codes** | NHA | NHA | NHA | DZE, NHA | DZE | NHA |
| **Intended Use** | Functional and esthetic rehabilitation of the edentulous mandible or maxilla | Functional and esthetic rehabilitation of the edentulous mandible or maxilla | Functional and esthetic rehabilitation of the edentulous mandible or maxilla | Functional and esthetic rehabilitation of the edentulous mandible or maxilla | Functional and esthetic rehabilitation of the edentulous mandible or maxilla | Functional and esthetic rehabilitation of the edentulous mandible or maxilla |
| **Designs/Features** | | | | | | |
| Abutment Design | CAD-CAM Titanium Base Abutments | CAD-CAM Titanium Base Abutments<br>CAD-CAM Cobalt Base Abutments<br>CAD-CAM Titanium Blank Abutments | CAD-CAM Titanium Base Abutments<br>CAD-CAM Titanium Blank Abutments | | | CAD-CAM Titanium Base Abutments |
| Restoration | Single-unit<br>Multi-unit | Single-unit<br>Multi-unit | Single-unit<br>Multi-unit | | | Single-unit<br>Multi-unit |
| Prosthesis Attachment | Cement-retained<br>Screw-retained | Cement-retained<br>Screw-retained | Cement-retained | | | Cement-retained<br>Screw-retained |
| Abutment-Implant Interface | Internal | Internal | Internal | Internal | Internal | Internal |
| | | | | | | |
| Abutment-Implant Platform Diameter, mm | 3.5, 4.0, 4.5, 5.0 | 2.8 – 5.0 | 3.5 – 5.0 | 4.0 | 3.5, 4.5, 5.0, 6.0 | 3.0 – 6.0 |
| Prosthetic Platform Diameter, mm | 4.1, 4.3, 4.75, 5.25 | 3.9– 6.5 | *Not stated in 510(k) Summary* | | | *Not stated in 510(k) Summary* |
| Superstructure (Coping) Design Parameters | | | | | | |
| Minimum wall thickness, mm | 0.43 | 0.5 | 0.5 or 0.7 | | | *Not stated in 510(k) Summary* |
| Minimum post height for single-unit restorations, mm | 4.0 | 4.0 | 4.0 | | | *Not stated in 510(k) Summary* |
| Minimum gingival height (of the coping), mm | 0<br>All bases have GH of 0.7 mm | 0.5 | *Not stated in 510(k) Summary* | | | *Not stated in 510(k) Summary* |
| Maximum gingival height (of the coping), mm | 5.83 | 6.7 | 5.0 | | | *Not stated in 510(k) Summary* |
| Angulation of Finished Abutment | Up to 30° | Up to 30° | Up to 20° | | | Up to 20° |
| Cement to bond coping to base | G-CEM LinkAce™<br>GC America Inc. | Multilink Hybrid Abutment Cement<br>Ivoclar Vivadent AG | *Not stated in 510(k) Summary* | | | *Not stated in 510(k) Summary* |
| **Materials** | | | | | | |
| Abutment Materials | Titanium alloy, ASTM F136 | Titanium alloy, ASTM F136<br>Cobalt-chromium alloy, ASTM F1537 | Titanium alloy, ASTM F136 | | | Titanium alloy, ASTM F136 |
| Coping | Zirconia, ISO 13356 | Zirconia, ISO 13356 | Zirconia, ISO 13356 | | | Zirconia, ISO 13356 |
| Abutment Screws | Titanium alloy, ASTM F136 | | Titanium alloy, ASTM F136 | | | Titanium alloy, ASTM F136 |