Imagine Milling Technologies, LLC
% Kevin Thomas
Vice President & Director of Regulatory Affairs
PaxMed International, LLC
12264 EL Camino Real, Suite 400
San Diego, California 92130

December 1, 2022

Re: K222368
Trade/Device Name: MIST IC
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 3, 2022
Received: November 3, 2022

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,

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)*
K222368

Device Name
MIST IC

Indications for Use *(Describe)*

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:

Compatible Implant Systems	Implant Body Diameter, mm	Implant Platform, mm
Biomet 3i OSSEOTITE® Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
	6.0	6.0
NobelActive® (conical connection)	3.5	3.5 (NP)
	4.3, 5.0	3.9 (RP)
	5.5	5.1 (WP)
NobelReplace Conical Connection	3.5	3.5 (NP)
	4.3, 5.0	3.9 (RP)
NobelParallel Conical Connection	3.75	3.5 (NP)
	4.3, 5.0	3.9 (RP)
	5.5	5.1 (WP)
Replace Select Tapered TiUnite	3.5	3.5 (NP)
	4.3	4.3 (RP)
	5.0	5.0 (WP)
	6.0	6.0
Replace Select Tapered PMC	3.5	3.5 (NP)
	4.3	4.3 (RP)
	5.0	5.0 (WP)
	6.0	6.0
Replace Select TC	3.5	3.5 (NP)
	4.0	4.3 (RP)
Zimmer Screw-Vent®	3.7	3.5
	4.7	4.5
Zimmer Tapered Screw-Vent®	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

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.

MIST IC abutments for Biomet 3i Certain 3.25 mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

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.

Department of Health and Human Services
Food and Drug Administration

Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K222368

MIST IC

Imagine Milling Technologies, LLC

November 30, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Imagine Milling Technologies, LLC 14220 Sullyfield Circle, Suite B Chantilly, VA 20151 Telephone +1 888-635-4999
Official Contact	Felix Chung, CEO
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	MIST IC
Common Name	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K182246, MIST IC, Imagine Milling Technologies, LLC

Reference Devices
K063341, 3i OSSEOTITE® Certain® Dental Implants, Implant Innovations, Inc.
K142260, NobelActive®, Nobel Biocare AB
K073142, NobelReplace Hexagonal Implants, Nobel Biocare AB
K173418, NobelParallel™ Conical Connection, Nobel Biocare AB
K050705, TiUnite® Implants, Nobel Biocare AB
K050406, NOBELSPEEDY™ Implants, Nobel Biocare USA LLC
K050258, Groovy Implants, Nobel Biocare AB

K023113, Replace TiUnite Endosseous Implant, Nobel Biocare USA, Inc.
K013227, Screw Vent Implant; Tapered Screw Vent Implant, Sulzer Dental, Inc.
K072589, Tapered Screw-Vent Implant, 4.1 mmD, Zimmer Dental, Inc.

INDICATIONS FOR USE STATEMENT

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:

Compatible Implant Systems	Implant Body Diameter, mm	Implant Platform, mm
Biomet 3i OSSEOTITE® Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
	6.0	6.0
NobelActive® (conical connection)	3.5	3.5 (NP)
	4.3, 5.0	3.9 (RP)
	5.5	5.1 (WP)
NobelReplace Conical Connection	3.5	3.5 (NP)
	4.3, 5.0	3.9 (RP)
NobelParallel Conical Connection	3.75	3.5 (NP)
	4.3, 5.0	3.9 (RP)
	5.5	5.1 (WP)
Replace Select Tapered TiUnite	3.5	3.5 (NP)
	4.3	4.3 (RP)
	5.0	5.0 (WP)
	6.0	6.0
Replace Select Tapered PMC	3.5	3.5 (NP)
	4.3	4.3 (RP)
	5.0	5.0 (WP)
	6.0	6.0
Replace Select TC	3.5	3.5 (NP)
	4.0	4.3 (RP)
Zimmer Screw-Vent®	3.7	3.5
	4.7	4.5
Zimmer Tapered Screw-Vent®	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

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.

MIST IC abutments for Biomet 3i Certain 3.25 mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

SUBJECT DEVICE DESCRIPTION

MIST IC from Imagine Milling Technologies, LLC is a line of Ti-base and machinable blank abutments to interface with compatible dental implants from 3 manufacturers, a total of 14 implant-abutment interface compatibilities. The compatible implant body diameters range from 3.25 mm to 6.0 mm and the corresponding implant platform diameters range from 3.4 mm to 6.0 mm. The subject device prosthetic

platform diameters range from 3.8 mm to 6.0 mm. All stock subject device components (abutments and abutment screws) are made of titanium alloy conforming to ASTM F136. The subject device MIST IC L-LINK abutments have a TiN coating achieved through a physical vapor deposition (PVD) process that is identical to the process used for TiN coating of Imagine Milling Technologies, LLC devices cleared in K182246. The PVD cathodic arc evaporation process is a high current, low voltage process in which material evaporated from the cathode (Ti) is ionized, transported through the vacuum chamber with reactive gas (N_2) and deposited as a non-porous, thin film on the titanium substrate.

Each abutment is supplied with the non-sterile abutment screw designed for attachment to the corresponding compatible OEM implant.

All patient-specific abutment fabrication for all MIST IC abutments is by prescription on the order of the clinician. All MIST IC abutments are intended to be milled at an Imagine Milling Technologies, LLC validated milling center under FDA quality system regulations.

MIST IC L-LINK abutments are two-piece abutments to be used as a base when fabricating a CAD-CAM customized restoration where the superstructure produced will compose the second part of the two-piece abutment; the assembly becoming a final finished medical device after cementation on the subject device abutment. They are provided in straight designs, with engaging and non-engaging connections.
The L-LINK abutments and corresponding zirconia superstructure are provided to the clinician either with the superstructure cemented to the abutment by the dental laboratory, or separately for the clinician to bond together chairside using the cement recommended in the labeling (RelyX RMGIP bonding cement, cleared in K022476).

Design parameters for the L-LINK zirconia superstructure are:
- Minimum wall thickness – 0.5 mm
- Minimum post height for single-unit restoration – 4.0 mm
- Minimum gingival height of the coping – 0 mm
  (all L-LINK bases have minimum gingival height of 0.5 mm)
- Maximum gingival height – 5.0 mm
- Maximum angle – 20°

All zirconia copings (superstructures) for use with the subject device MIST IC L-LINK abutments will conform to ISO 13356.

MIST IC PREFIT abutments are cylindrical abutments designed for patient-specific abutment fabrication by a CAD-CAM process and machined into a one-piece, all titanium abutment. The portion of the abutment available for milling is either 9.9 mm in diameter by 20 mm in length or 13.9 mm in diameter by 20 mm in length. MIST IC PREFIT abutments have an engaging connection.

Design parameters for the PREFIT patient specific abutment are:
- Minimum wall thickness – 0.5 mm
- Minimum post height for single-unit restoration – 4.0 mm
- Minimum gingival height – 0.5 mm
- Maximum gingival height – 5.0 mm
- Maximum angle – 30°

PERFORMANCE DATA

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

non-clinical analysis performed to evaluate the metallic subject devices and the compatible OEM implant bodies in the MR environment using scientific rationale and published literature (TO Woods, JG Delfino, and S Rajan, *"Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices," Journal of Testing and Evaluation*, Volume 49, No. 2, 2021, pp. 783-795); the analysis addressed parameters per the FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (issued May 2021) including magnetically induced displacement force and torque;

sterilization validation according to ISO 17665-1 and ISO 17665-2;

biocompatibility according to ISO 10993-5 and ISO 10993-12;

reverse engineering of OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility;

and static and dynamic compression-bending 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 K182246. The subject device and the primary predicate device are intended to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. Provided at the end of this summary are tables comparing the Indications for Use Statements (IFUS) and the technological characteristics of the subject device and the primary predicate device.

All additional reference devices are identified for OEM implant body compatibilities.

The IFUS for the subject device is nearly identical to that of the primary predicate device K182246. The minor differences in language of the subject device and primary predicate device include the compatible implant systems and, therefore, do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function. An additional difference is that the subject device IFUS includes language that the subject abutments for Biomet 3i Certain 3.25 mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only. This language is included in the IFUS to support substantial equivalence of the Biomet 3i Certain compatibility as related to the performance bench testing provided in this submission.

The subject device (MIST IC L-LINK and MIST IC PREFIT) and primary predicate device K182246 are indicated for use with CAD-CAM technology to fabricate patient-specific abutments prescribed by the clinician. The subject device and the primary predicate device require that digital files for CAD-CAM fabricated abutments be sent to a Imagine Milling Technologies, LLC validated milling center for manufacture.

The subject device (MIST IC L-LINK) is substantially equivalent to the primary predicate K182246 MIST IC L-LINK in material, design, and function. Both are manufactured from titanium alloy (conforming to ASTM F136) with a titanium nitride (TiN) coating, both base designs require a zirconia superstructure that is cement-retained only, and both have the same range of angulation (up to 20°). The design parameters for the subject device MIST IC L-LINK zirconia superstructure are identical to the limits of fabrication for the primary predicate K182246.

The subject device MIST IC L-LINK differs from the primary predicate K182246 MIST IC L-LINK in the range of platform diameters and abutment-implant interfaces. These differences do not impact safety or

effectiveness because they are related to the compatible OEM implant designs and are mitigated by testing of the subject device constructs in conformance with ISO 14801.

The subject device MIST IC PREFIT is substantially equivalent to the K182246 MIST IC PREFIT in material, design, and function. Both are for cement-retained, single-unit or multi-unit restorations. Both are manufactured from titanium alloy (conforming to ASTM F136) and are for CAD-CAM fabrication of a one-piece, patient-specific abutment. The subject device MIST IC PREFIT and the K182246 MIST IC PREFIT abutments have the same range of angulation (up to 30°). The design parameters for the subject device MIST IC PREFIT patient specific abutment are identical to the limits of fabrication for the primary predicate K182246.

The subject device MIST IC PREFIT differs from the primary predicate K182246 MIST IC PREFIT in the range of platform diameters and abutment-implant interfaces. These differences do not impact safety or effectiveness because they are related to the compatible OEM implant designs and are mitigated by testing of the subject device constructs in conformance with ISO 14801.

The subject device MIST IC L-LINK and MIST IC PREFIT stock abutments are made of titanium alloy conforming to ASTM F136. The titanium alloy subject device components are manufactured from identical materials, in identical facilities using the identical manufacturing processes as used for Imagine Milling Technologies, LLC products cleared previously in the K182246. The subject device MIST IC L-LINK abutments have a TiN coating achieved through a physical vapor deposition (PVD) process that is identical to the TiN coating on devices previously cleared in Imagine Milling Technologies, LLC primary predicate K182246. No dyes or coloring additives are used.

The subject device MIST IC L-LINK abutments are to be used with copings fabricated from zirconia conforming to ISO 13356. This is the same material used for copings in the primary predicate device K182246. The recommended bonding cement for the subject device MIST IC L-LINK zirconia superstructures is RelyX RMGIP cleared in K022476, the same cement recommended for bonding the copings in the primary predicate device K182246.

Compatibility testing was performed for each of the compatible OEM implant system interfaces (platforms). For each of the compatible OEM implant system interfaces, critical dimensions were identified and were measured from samples of OEM implants, OEM abutments, and OEM abutment screws. The key dimensional data measured from the OEM components were used to establish tolerances for corresponding subject device abutments and abutment screws to ensure that the subject device components are compatible with the corresponding OEM implant system connections.

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 and abutment screws, fabricated to the limits stated in the proposed labeling, in combination with previously cleared compatible OEM implants have sufficient strength for their intended use.

Minor differences in the designs, dimensions, sizes, or compatible implant lines between the subject device and the primary predicate device do not affect substantial equivalence. These minor differences do not impact substantial equivalence because these differences are related to the compatible OEM implant designs.

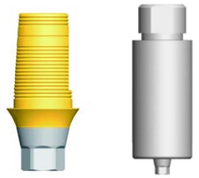
CONCLUSION

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

Comparison of Indications for Use Statements

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Subject Device</td><td></td></tr>
<tr><td>K222368
MIST IC
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:
<table>
<tr><th>Compatible Implant Systems</th><th>Implant Body Diameter, mm</th><th>Implant Platform, mm</th></tr>
<tr><td rowspan="4">Biomet 3i OSSEOTITE® Certain®</td><td>3.25</td><td>3.4</td></tr>
<tr><td>4.0</td><td>4.1</td></tr>
<tr><td>5.0</td><td>5.0</td></tr>
<tr><td>6.0</td><td>6.0</td></tr>
<tr><td rowspan="3">NobelActive®
(conical connection)</td><td>3.5</td><td>3.5 (NP)</td></tr>
<tr><td>4.3, 5.0</td><td>3.9 (RP)</td></tr>
<tr><td>5.5</td><td>5.1 (WP)</td></tr>
<tr><td rowspan="2">NobelReplace Conical Connection</td><td>3.5</td><td>3.5 (NP)</td></tr>
<tr><td>4.3, 5.0</td><td>3.9 (RP)</td></tr>
<tr><td rowspan="3">NobelParallel Conical Connection</td><td>3.75</td><td>3.5 (NP)</td></tr>
<tr><td>4.3, 5.0</td><td>3.9 (RP)</td></tr>
<tr><td>5.5</td><td>5.1 (WP)</td></tr>
<tr><td rowspan="4">Replace Select Tapered TiUnite</td><td>3.5</td><td>3.5 (NP)</td></tr>
<tr><td>4.3</td><td>4.3 (RP)</td></tr>
<tr><td>5.0</td><td>5.0 (WP)</td></tr>
<tr><td>6.0</td><td>6.0</td></tr>
<tr><td rowspan="4">Replace Select Tapered PMC</td><td>3.5</td><td>3.5 (NP)</td></tr>
<tr><td>4.3</td><td>4.3 (RP)</td></tr>
<tr><td>5.0</td><td>5.0 (WP)</td></tr>
<tr><td>6.0</td><td>6.0</td></tr>
<tr><td rowspan="2">Replace Select TC</td><td>3.5</td><td>3.5 (NP)</td></tr>
<tr><td>4.0</td><td>4.3 (RP)</td></tr>
<tr><td rowspan="2">Zimmer Screw-Vent®</td><td>3.7</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td></tr>
<tr><td rowspan="3">Zimmer Tapered Screw-Vent®</td><td>3.7, 4.1</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td></tr>
<tr><td>6.0</td><td>5.7</td></tr>
</table>
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.
MIST IC abutments for Biomet 3i Certain 3.25 mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.</td></tr>
<tr><td>Primary Predicate Device</td><td>Indications for Use Statement</td></tr>
<tr><td>K182246
MIST IC
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:
<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>
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>
</table>

Comparison of Technological Characteristics

Features	Subject Device	Primary Predicate Device
	K222368 MIST IC Imagine Milling Technologies, LLC	K182246 MIST IC Imagine Milling Technologies, LLC
		
Reason for Predicate Device	**Not applicable**	**Abutment designs, materials, manufacturing, sterilization**
Designs		
Abutment Designs	CAD-CAM Titanium Base (L-LINK) CAD-CAM Titanium Blank (PREFIT)	CAD-CAM Titanium Base (L-LINK, S-LINK) CAD-CAM Titanium Blank (PREFIT)
Restoration	Single-Unit Multi-Unit	Single-Unit Multi-Unit
Prosthesis Attachment	Cement-retained	Cement-retained
Base Abutment Design Parameters for Zirconia Superstructure		
Minimum wall thickness, mm	0.5	0.5
Minimum post height for single-unit restoration, mm	4.0	4.0
Minimum gingival height, mm	0 (all bases have minimum gingival height of 0.5 mm)	0 (all bases have minimum gingival height of 0.6 mm)
Maximum gingival height, mm	5.0	5.0
Angulation	Up to 20°	Up to 20°
Recommended Cement to bond superstructure to base	3M ESPE RelyX Unicem bonding cement, cleared in K022476 as RelyX RMGIP	3M ESPE RelyX Unicem bonding cement, cleared in K022476 as RelyX RMGIP
Blank Abutment – Finished Design Parameters		
Minimum wall thickness, mm	0.5	0.5
Minimum post height for single-unit restoration, mm	4.0	4.0
Minimum gingival height, mm	0.5	*Not provided in 510(k) Summary*
Maximum gingival height, mm	5.0	5.0
Angulation	Up to 30°	Up to 30°
Abutment/Implant Platform Diameter, mm	3.4 – 6.0	3.5 – 5.0
Abutment/ Implant Interface	Internal	Internal
Materials		
Abutments	Titanium Alloy (ASTM F136) Zirconia, copings (ISO 13356)	Titanium Alloy (ASTM F136) Zirconia, copings (ISO 13356)
Screws	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)
How Provided		
Sterility	Non-Sterile	Non-Sterile
Sterilization Method	Moist Heat	Moist Heat
Usage	Single patient, single use	Single patient, single use