June 27, 2026

Imagine Milling Technologies, LLC
% Kevin Thomas
VP and Director of Regulatory Affairs
PaxMed International, LLC
1925 Palomar Oaks Way
Suite 210
Carlsbad, California 92008

Re: K261122
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: April 3, 2026
Received: April 3, 2026

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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ANDREW I. STEEN -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)* K261122

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 Line	Implant Body Diameter, mm	Prosthetic Connection, mm
SICace (Internal hex)	3.4	3.3
	4.0	
	4.5	4.2
	5.0	
SICmax (Internal hex)	3.7	3.3
	4.2	
	4.7	4.2
	5.2	
SICtapered (Internal hex)	3.7	3.3
	4.2	
	4.7	4.2
	5.2	

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K261122
MIST IC
Imagine Milling Technologies, LLC June 23, 2026

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 1925 Palomar Oaks Way, Suite 210 Carlsbad, CA 92008 Telephone +1 858-792-1235 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	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Dental and ENT Devices

PREDICATE AND REFERENCE DEVICE INFORMATION

Primary Predicate Device
K243009, MIST IC, Imagine Milling Technologies, LLC

Reference Devices
K182246, MIST IC, Imagine Milling Technologies, LLC
K022476, RelyX RMGIP, 3M ESPE

Reference Devices for OEM implant body clearances
K173207, SIC invent Dental Implant Systems, SIC invent AG
K210489, SICtapered & SICvantage tapered, SIC invent AG

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 Line	Implant Body Diameter, mm	Prosthetic Connection, mm
SICace (Internal hex)	3.4	3.3
	4.0	
	4.5	4.2
	5.0	
SICmax (Internal hex)	3.7	3.3
	4.2	
	4.7	4.2
	5.2	
SICtapered (Internal hex)	3.7	3.3
	4.2	
	4.7	4.2
	5.2	

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.

SUBJECT DEVICE DESCRIPTION

MIST IC abutments include three abutment designs, L-LINK, A-LINK, and PREFIT, having connections compatible with dental implants from SIC invent AG, as listed in the Indications for Use Statement.

All subject device L-LINK and A-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. The zirconia superstructure will be fabricated using a CAD-CAM process. A-LINK has a cut out in the prosthetic post to accommodate a restoration with an angled screw channel when clinically necessary. L-LINK and A-LINK abutments are provided with engaging and non-engaging implant connections. PREFIT abutments are titanium cylindrical abutments designed for patient specific abutment fabrication using a CAD-CAM process. All PREFIT abutments have an engaging implant connection.

All stock subject device components (abutments and abutment screws) are made of titanium alloy conforming to ASTM F136. The subject device L-LINK and A-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 K243009. 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 a non-sterile abutment screw, also TiN coated, designed for attachment to the corresponding compatible OEM implant.

All patient-specific abutment fabrication for 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.

The L-LINK and A-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 required in the labeling (RelyX RMGIP bonding cement, cleared in K022476).

The design parameters for L-LINK patient-specific abutments are:
- Minimum wall thickness – 0.5 mm
- Minimum abutment post height for single-unit restoration – 4.0 mm
  (abutment post height is measured above the gingival height of the final patient-matched design)
- Minimum gingival height – 0.8 mm
- Maximum gingival height – 6.0 mm
  - Maximum gingival height in zirconia superstructure – 5.2 mm
  - Gingival height in the L-LINK base – 0.8 mm
- Maximum angle – 20°

The design parameters for A-LINK patient-specific abutments are:
- Minimum wall thickness – 0.5 mm
- Minimum abutment post height for single-unit restoration – 4.35 mm
  (abutment post height is measured above the gingival height of the final patient-matched design)
- Minimum gingival height – 1.3 mm
- Maximum gingival height – 6.0 mm
  - Maximum gingival height in zirconia superstructure – 4.7 mm
  - Gingival height in the A-LINK base – 1.3 mm
- Maximum angle – 20°

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

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. All PREFIT abutments have an engaging connection.

The design parameters for PREFIT patient-specific abutments are:
- Minimum wall thickness – 0.5 mm
- Minimum abutment post height for single-unit restoration – 4.0 mm
  (abutment post height is measured above the gingival height of the final patient-matched design)
- 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:

- provided in this submission was a non-clinical worst-case MRI review to evaluate the subject device components in the MR environment using scientific rationale and published literature (T.O. Woods,

J.G. 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 (March/April 2021): 783–795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition, and the rationale addressed parameters per the FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, including magnetically induced displacement force and torque;

- referenced from K243009 (provided in K182246) was moist heat sterilization for subject devices provided non-sterile to the end user, validated to a sterility assurance level of 10^{-6} by the overkill method according to ISO 17665-1 and ISO TS 17665-2;
- referenced from K243009 and K182246 was biocompatibility according to ISO 10993-1;
- referenced from K243009 was testing performed on the TiN coating, including scratch testing, shear strength testing according to ASTM F1044, and tensile adhesion testing according to ASTM F1147;
- provided in this submission was documentation of the compatibility of the subject device abutments with the SICace, SICmax, and SICtapered implants based on a contractual agreement and working relationship between Imagine Milling Technologies, LLC and SIC invent AG;
- provided in this submission was mechanical testing conducted according to ISO 14801 to support the performance of the subject device abutments in conjunction with the compatible OEM implants.

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 K243009 and the reference device K182246. The subject device, the primary predicate device K243009, and the reference device K182246 are intended to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. Provided at the end of this summary is a table comparing the Indications for Use Statements (IFUS) and the technological characteristics of the subject device, the primary predicate device K243009, and the reference device K182246.

All additional reference devices are for the cement required to bond the zirconia superstructure to the L-LINK and A-LINK abutment and for the compatible OEM implant body clearances.

Intended Use

The subject device is substantially equivalent in intended use to the primary predicate device K243009 and the reference device K182246. The subject device, the primary predicate device K243009, and the reference device K182246 all are intended to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible.

The Indications for Use Statement (IFUS) for the subject device, the primary predicate device K243009, and the reference device K182246 are identical except for the list of compatible OEM implants. This minor difference does not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function.

The subject device abutments, the abutments cleared in the primary predicate device K243009, and the abutments cleared in the reference device K182246 all are indicated for use with CAD-CAM technology to fabricate patient-specific abutments prescribed by the clinician. The subject device, primary predicate device K243009, and the reference device K182246 all require that digital files for fabrication patient-specific CAD-CAM abutments be sent to an Imagine Milling Technologies, LLC validated milling center for manufacture.

Design, Materials and Technological Characteristics

The subject device L-LINK abutments are substantially equivalent to the L-LINK abutments cleared in the primary predicate K243009 and the reference device K182246 in material, design, and function. The subject device A-LINK abutments are substantially equivalent to the S-LINK abutments cleared in the reference device K182246 in material, design, and function. All are manufactured from titanium alloy conforming to ASTM F136, with a titanium nitride (TiN) coating, and all require a cement-retained zirconia superstructure.

The subject device L-LINK abutments are substantially equivalent to the L-LINK abutments cleared in the primary predicate K243009 and the reference device K182246 in terms of the maximum abutment diameter (prosthetic platform diameter), and a zirconia superstructure that has the same minimum wall thickness (0.5 mm) and the same range of angulation (up to 20°).

The subject device A-LINK abutments are substantially equivalent to the S-LINK abutments cleared in the reference device K182246 in terms of the maximum abutment diameter (prosthetic platform diameter), and a zirconia superstructure that has a similar minimum wall thickness (0.5 mm and 0.7 mm) and the same range of angulation (up to 20°).

The clinical risks associated with the subject device L-LINK and A-LINK abutments with angulation in the final, finished form, including the differences in the design parameters for the zirconia superstructures compared to the primary predicate device and the reference device, are mitigated by mechanical testing performed in conformance with ISO 14801.

The subject device PREFIT abutments are substantially equivalent to the PREFIT abutments cleared in the primary predicate K243009 and the reference device K182246 in material, design, and function. All are manufactured from titanium alloy conforming to ASTM F136, and have the same design parameters for the final, finished abutment including the minimum wall thickness (0.5 mm), minimum gingival height (0.5 mm), and maximum angulation (up to 30°).

The clinical risks associated with the subject device PREFIT abutments with angulation in the final, finished form, are mitigated by the mechanical testing performed in conformance with ISO 14801.

The subject device L-LINK, A-LINK, and PREFIT abutments, and the corresponding abutment screws are made of titanium alloy conforming to ASTM F136. The titanium alloy subject device components are manufactured from identical materials, in identical facilities using identical manufacturing processes as those used for the Imagine Milling Technologies, LLC products previously cleared in the primary predicate K243009. The subject device L-LINK abutments, A-LINK abutments, and the abutment screws for clinical use have a TiN coating achieved through a physical vapor deposition (PVD) process that is identical to the TiN coating on devices previously cleared in the primary predicate K243009.

The subject device 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 K243009. The recommended bonding cement for the subject device zirconia superstructures is 3M ESPE RelyX Unicem bonding cement, cleared in K022476 as RelyX RMGIP, the same cement recommended for bonding the copings in the primary predicate device K243009.

The subject device L-LINK, A-LINK, and PREFIT abutments, and the corresponding abutment screws are provided non-sterile, and provided in the same packaging as the primary predicate device K243009. The proposed labeling includes instructions for moist heat sterilization to be performed by the end user. The validated sterilization instructions are leveraged from the reference device K182246.

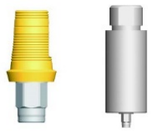
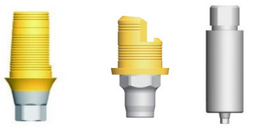
Mechanical performance testing of the subject device was performed in conformance to ISO 14801. The fatigue limit data demonstrated that constructs of the subject device abutments and abutment screws, fabricated to the limits stated in the proposed labeling, in combination with previously cleared compatible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

CONCLUSION

The subject device has the same intended use, has similar technological characteristics, and is made of the same materials as the primary predicate device K243009 and the reference device K182246. The subject device encompasses the same range of physical dimensions, is packaged in the same materials, and is to be sterilized using the same methods as the primary predicate device K243009 and reference device K182246. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

The basis for the belief of Imagine Milling Technologies, LLC that the subject device is substantially equivalent to the predicate device K243009 and the reference device K182246 is summarized in the following *Table of Substantial Equivalence.*

Table of Substantial Equivalence

<table>
<tr><th rowspan="2">Features</th><th>Subject Device</th><th>Primary Predicate Device</th><th>Reference Device</th></tr>
<tr><th>MIST IC
Imagine Milling Technologies, LLC</th><th>K243009
MIST IC
Imagine Milling Technologies, LLC</th><th>K182246
MIST IC
Imagine Milling Technologies, LLC</th></tr>
<tr><td>Representative images
not to scale</td><td>  </td><td>  </td><td>  </td></tr>
<tr><td>Indications for Use Statement</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 Line</th><th>Implant Body Diameter, mm</th><th>Prosthetic Connection, mm</th></tr>
<tr><td rowspan="4">SICace
(Internal hex)</td><td>3.4</td><td rowspan="2">3.3</td></tr>
<tr><td>4.0</td></tr>
<tr><td>4.5</td><td rowspan="2">4.2</td></tr>
<tr><td>5.0</td></tr>
<tr><td rowspan="4">SICmax
(Internal hex)</td><td>3.7</td><td rowspan="2">3.3</td></tr>
<tr><td>4.2</td></tr>
<tr><td>4.7</td><td rowspan="2">4.2</td></tr>
<tr><td>5.2</td></tr>
<tr><td rowspan="4">SICtapered
(Internal hex)</td><td>3.7</td><td rowspan="2">3.3</td></tr>
<tr><td>4.2</td></tr>
<tr><td>4.7</td><td rowspan="2">4.2</td></tr>
<tr><td>5.2</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><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:

<complete list is provided in the K243009 510(k) Summary>

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><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:

<complete list is provided in the K182246 510(k) Summary>

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>Reason for Predicate Device</td><td>Not applicable</td><td>Abutment designs, materials, manufacturing, sterilization</td><td>Abutment designs, materials, manufacturing, sterilization</td></tr>
<tr><td>Product Code</td><td>NHA</td><td>NHA</td><td>NHA</td></tr>
<tr><td colspan="4">Designs</td></tr>
<tr><td>Abutment Designs</td><td>CAD-CAM Titanium Bases: L-LINK, A-LINK
CAD-CAM Titanium Blank: PREFIT</td><td>CAD-CAM Titanium Bases: L-LINK
CAD-CAM Titanium Blank: PREFIT</td><td>CAD-CAM Titanium Bases: L-LINK, S-LINK
CAD-CAM Titanium Blank: PREFIT</td></tr>
<tr><td>Restoration</td><td>Single-Unit
Multi-Unit</td><td>Single-Unit
Multi-Unit</td><td>Single-Unit
Multi-Unit</td></tr>
<tr><td>Prosthesis Attachment</td><td>Cement-retained</td><td>Cement-retained</td><td>Cement-retained</td></tr>
<tr><td>Abutment/ Implant Interface</td><td>Internal</td><td>Internal</td><td>Internal</td></tr>
<tr><td colspan="4">L-LINK Titanium Base Abutments</td></tr>
<tr><td>Post Height (length above gingival height)</td><td>5.3 mm</td><td>4.7 – 5.5 mm</td><td>5.3 mm</td></tr>
<tr><td>Abutment diameter
(Prosthetic platform diameter)</td><td>4.0 mm, 4.5 mm</td><td>3.8 – 6.9 mm</td><td>4.0 – 4.8 mm</td></tr>
</table>

Features	Subject Device **MIST IC** **Imagine Milling Technologies, LLC**	Primary Predicate Device **K243009** **MIST IC** **Imagine Milling Technologies, LLC**	Reference Device **K182246** **MIST IC** **Imagine Milling Technologies, LLC**
A-LINK Titanium Base Abutments			**S-LINK Titanium Base Abutments**
Post Height (length above gingival height)	6.0 mm / 2.0 mm		3.8 mm / 2.2 mm
Abutment diameter (Prosthetic platform diameter)	4.2 mm, 4.5 mm		4.0 – 4.8 mm
Design Parameters for Zirconia Superstructure			
Minimum wall thickness	0.5 mm	0.5 mm	0.5 mm (L-LINK) 0.7 mm (S-LINK)
Minimum abutment post height for single-unit restoration (abutment post height is measured above the gingival height of the final patient-matched design)	4.0 mm (L-LINK) 4.35 mm (A-LINK)	4.0 mm	4.0 mm
Minimum gingival height	0 mm (all L-LINK bases have minimum gingival height of 0.8 mm, all A-LINK bases have minimum gingival height of 1.3 mm)	0 mm (all bases have minimum gingival height of 0.5 mm)	0 mm (all bases have minimum gingival height of 0.5 mm)
Maximum gingival height	6.0 mm L-LINK – 5.2 mm in the zirconia, 0.8 mm in the base A-LINK – 4.7 mm in the zirconia, 1.3 mm in the base	6.0 mm	5.0 mm
Angulation	Up to 20°	Up to 20°	Up to 20°
Cement required in labeling 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	3M ESPE RelyX Unicem bonding cement, cleared in K022476 as RelyX RMGIP
PREFIT Blank Abutment – Finished Design Parameters			
Abutment diameter (Prosthetic platform diameter)	Depends on available interproximal space	Depends on available interproximal space	Depends on available interproximal space
Minimum wall thickness	0.5 mm	0.5 mm	0.5 mm
Minimum abutment post height for single-unit restoration (abutment post height is measured above the gingival height of the final patient-matched design)	4.0 mm	4.0 mm	4.0 mm
Minimum gingival height	0.5 mm	0.5 mm	0.5 mm
Maximum gingival height	5.0 mm	6.0 mm	5.0 mm
Angulation	Up to 30°	Up to 30°	Up to 30°
Materials			
Abutments	Titanium Alloy (ASTM F136) Zirconia, copings (ISO 13356)	Titanium Alloy (ASTM F136) Zirconia, copings (ISO 13356)	Titanium Alloy (ASTM F136) Zirconia, copings (ISO 13356)
Abutment Surface	TiN coating (Ti-bases)	TiN coating (Ti Bases)	TiN coating (Ti Bases)
Screws	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)
How Provided			
Sterility	Non-Sterile	Non-Sterile	Non-Sterile
Sterilization Method	Moist Heat	Moist Heat	Moist Heat
Usage	Single patient, single-use	Single patient, single-use	Single patient, single-use