June 16, 2025

GeoMedi Co., Ltd.
% Floyd Larson
President
PaxMed International, LLC
1925 Palomar Oaks Way
Suite 210
Carlsbad, California 92008

Re: K242978
Trade/Device Name: Geo Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 13, 2025
Received: May 14, 2025

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

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

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

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

K242978

Device Name

Geo Abutment

Indications for Use *(Describe)*

Geo 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. Geo Abutments are compatible with the following implants.

Compatible Implant Systems

Compatible Implant Systems	GeoMedi Code for OEM	Implant Body Diameter, mm	Implant/Abutment Connection
Dentium Superline	DER	3.6, 4.0, 4.5, 5.0, 5.8	Universal
DIO UF II	SURD	3.8, 4.0, 4.5, 5.0, 5.5, 5.9, 6.4, 6.9	Universal
Hiossen ETIII SA Mini	SUM	3.75, 3.77	TS Mini
Hiossen ETIII SA	SURO	4.25, 4.65, 4.63, 4.6, 5.1, 5.08, 5.05	TS Regular
Hiossen ETIII SA Ultra-Wide		5.9, 5.92, 5.95, 6.0, 6.8, 6.82	
Megagen AnyOne Internal (normal thread, deep thread, special length)	DERA (MAO)	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3	Universal
Megagen AnyRidge Internal (normal ridge, deep ridge)	MARR	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4	Universal
Megagen MiNi Internal	MMN	3.0, 3.4	MINI

All digitally designed custom abutments for use with Geo Abutments are to be sent to a GeoMedi Co. Ltd. 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.

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510(k) Summary
K242978

GeoMedi Co., Ltd.
Geo Abutment

June 16, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name	GeoMedi Co., Ltd. # B112,702,703,704,705,709-1,810-2, 811 Indeokwon IT Valley, Unit D 40, Imi-no, Uiwang-si Gyeonggi-do, 16006 Republic of Korea Telephone +82-2-588-2871
Official Contact	Jihyo, Lee, Regulatory Affairs
Representative/Consultant	Floyd G. Larson, MS, MBA Kevin Thomas, PhD PaxMed International, LLC 1925 Palomar Oaks Way, Suite 210 Carlsbad, CA 92008 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: flarson@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	Geo Abutment
Common Name	Dental 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 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

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

Reference Device

K222368 MIST IC, Imagine Milling Technologies, LLC

Reference Devices for OEM Compatibilities

K160965 SuperLine, Dentium Co., Ltd.
K213599 SuperLine, Dentium Co., Ltd.
K170608 UF(II) Implant System, DIO Corporation
K173975 UF(II) Wide Fixture, DIO Corporation
K103537 ETIII SA Ultra wide System, HiOSSEN Inc.
K140934 HIOSSEN Implant System, HIOSSEN, Incorporated
K123988 AnyOne Internal Implant System, Megagen Implant Company, Ltd.
K110955 AnyRidge Internal Implant System, Megagen Implant Company, Ltd.
K140091 Xpeed AnyRidge Internal Implant System, MegaGen Implant Co., Ltd.
K150537 MiNi Internal Implant System, MegaGen Implant Co., Ltd.

INDICATIONS FOR USE STATEMENT

Geo 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. Geo Abutments are compatible with the following implants.

Compatible Implant Systems

Compatible Implant Systems	GeoMedi Code for OEM	Implant Body diameter, mm	Implant/Abutment Connection
Dentium Superline	DER	3.6, 4.0, 4.5, 5.0, 5.8	Universal
DIO UF II	SURD	3.8, 4.0, 4.5, 5.0, 5.5, 5.9, 6.4, 6.9	Universal
Hiossen ETIII SA Mini	SUM	3.75, 3.77	TS Mini
Hiossen ETIII SA	SURO	4.25, 4.65, 4.63, 4.6, 5.1, 5.08, 5.05	TS Regular
Hiossen ETIII SA Ultra-Wide		5.9, 5.92, 5.95, 6.0, 6.8, 6.82	
Megagen AnyOne Internal (normal thread, deep thread, special length)	DERA (MAO)	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3	Universal
Megagen AnyRidge Internal (normal ridge, deep ridge)	MARR	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4	Universal
Megagen MiNi Internal	MMN	3.0, 3.4	MINI

All digitally designed custom abutments for use with Geo Abutments are to be sent to a GeoMedi Co. Ltd. validated milling center for manufacture.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for Geo Abutment from GeoMedi Co., Ltd. a line of titanium base abutments (identified as Multibase) and machinable blank abutments (identified as CMFit*)* to interface with compatible dental implants from four (4) manufacturers, and a total of seven (7) implant-abutment connections. The compatible implant body diameters range from 3.0 mm to 8.0 mm. The subject device prosthetic platform diameters range from 4.0 mm to 4.6 mm. All patient-specific abutments prepared from subject device Geo Abutment are to be manufactured at a GeoMedi validated milling center.

Geo Multibase abutments are two-piece abutments in which the Geo Multibase Abutment comprises the first part of the two-piece abutment and a patient-specific zirconia superstructure comprises the second part; the assembly becoming a final finished medical device after cementation of the superstructure on the subject device abutment. They are provided in straight designs, and two (2) connection types: for single unit prostheses (engaging connection) and for bridge or multi-unit prostheses (non-engaging connection). They are not intended for angulation correction, as the design parameters for the superstructure are restricted to straight abutments only.

These abutments are made of titanium alloy (Ti-6Al-4V) with a titanium nitride (TiN) coating on the coronal portion of the external surface, not including the implant-abutment interface.
The Geo Multibase abutment 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 (3M ESPE RelyX Unicem bonding cement, cleared in K022476 as RelyX RMGIP).

All patient-specific custom zirconia superstructure fabrication is by prescription on the order of the clinician.

The design parameters for zirconia superstructures to be used with Geo Multibase abutments are:

- Minimum wall thickness – 0.5 mm
- Minimum cementable post height for single-unit restoration – 4.0 mm
  (minimum cementable post height for single-unit restoration is defined as the height above the restorative margin)
- Minimum gingival height of the superstructure – 0 mm
  (Geo Multibase abutments have minimum gingival height of 1.0 mm)
- Maximum gingival height – 5.0 mm
- Maximum angle – 0° (straight only)

All zirconia copings (superstructures) for use with the subject device Geo Multibase abutment will be made at a GeoMedi Co., Ltd. validated milling center under FDA quality system regulations, and the material will conform to ISO 13356, *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*.

Geo CMFit abutments are cylindrical titanium alloy abutments designed to be used for fabrication of a one-piece, all titanium patient-specific abutment by a CAD/CAM process. 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. Geo CMFit abutments are available in engaging and non-engaging connections.

All patient-specific abutment fabrication is by prescription on the order of the clinician. The design parameters for all CMFit patient-specific abutments are:

Minimum wall thickness – 0.65 mm
Minimum cementable post height for single-unit restoration – 4.0 mm
(minimum cementable post height for single-unit restoration is defined as the height above the restorative margin)
Minimum gingival height – 0.5 mm
Maximum gingival height – 5.0 mm
Maximum angle – 30°

Manufacture of the Geo Abutment CMFIT patient-specific abutment is to be performed at an GeoMedi Co., Ltd. validated milling center.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

- mechanical testing conducted according to ISO 14801 to demonstrate that the subject devices in combination with the compatible implants have sufficient strength for the intended use;
- shear and tension testing conducted to characterize the mechanical properties of the TiN coated surface as per ASTM F1044 and F1147 respectively.;
- reverse engineering dimensional analysis for the OEM compatibilities that are included in this submission, analyzing OEM implant bodies, OEM abutments, and OEM abutment screws to demonstrate that the subject device abutments are compatible with the respective OEM implants; and.
- sterilization validation according to ISO 17665-1 and ISO 17665-2.

Referenced from the primary predicate device K182246:

- biocompatibility evaluation according to ISO 10993-5 and ISO 10993-12.

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 attachment are tables comparing the Indications for Use Statements (IFUS) and the technological characteristics of the subject device, the primary predicate device K182246, and the reference device K222368.

The IFUS for the subject device is similar to that of the primary predicate device K182246. The minor differences in language of the subject device and primary predicate device are limited to 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.

The IFUS for the subject device also is nearly identical to that of the reference device K222368. The minor differences in language of the subject device and the reference device K222368 are limited to the compatible implant systems and the language concerning the required validated milling center. These minor differences do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function.
The subject device 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 GeoMedi Co., Ltd. validated milling center for manufacture.

The subject device Multibase is substantially equivalent to the L-Link of the primary predicate K182246 in material, design, and function. Both are manufactured from titanium alloy with a titanium nitride (TiN) coating and both base designs require a zirconia superstructure that is cement-retained only. Superstructures for the subject device Multibase are straight only, while the L-Link of the primary predicate K182246 may be used with superstructures having angulation up to 20°.

The subject device Multibase 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.

The subject device CMFit 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 and are for CAD-CAM fabrication of a one-piece, patient-specific abutment. The subject device CMFit and the K182246 MIST IC PREFIT abutments have the same range of angulation (up to 30°). The design parameters for the subject device patient-specific abutment are identical to the limits of fabrication for the primary predicate K182246 except for the greater minimum wall thickness for the subject device CMFit.

The subject device CMFit differs from the primary predicate K182246 MIST IC PREFIT in the range of 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 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*.

The subject device Multibase abutments are to be used with superstructures fabricated from zirconia conforming to ISO 13356 *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*. This is the same material used for superstructures in the primary predicate device K182246. The required bonding cement for the subject device Multibase zirconia superstructures is 3M ESPE RelyX Unicem bonding cement, cleared in K022476 as RelyX RMGIP, the same cement is required for bonding the superstructures in the primary predicate device K182246.

Minor differences in the designs, dimensions, sizes, or compatible implant systems 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.

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

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

The basis for the belief of GeoMedi Co., Ltd. that the subject device is substantially equivalent to the predicate devices is summarized in the following Table 1. *Table of Substantial Equivalence – Indications for Use Statements* and Table 2. *Table of Substantial Equivalence – Technological Characteristics*.

Table 1. Table of Substantial Equivalence – Indications for Use Statement

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Subject Device</td><td></td></tr>
<tr><td>Geo Abutment
GeoMedi Co., Ltd.</td><td>Geo 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. Geo Abutments are compatible with the following implants.
<table>
<tr><th>Compatible Implant Systems</th><th>GeoMedi Code for OEM</th><th>Implant Body, diameter, mm</th><th>Implant/Abutment Connection</th></tr>
<tr><td>Dentium Superline</td><td>DER</td><td>3.6, 4.0, 4.5, 5.0, 5.8</td><td>Universal</td></tr>
<tr><td>DIO UF II</td><td>SURD</td><td>3.8, 4.0, 4.5, 5.0, 5.5, 5.9, 6.4, 6.9</td><td>Universal</td></tr>
<tr><td>Hiossen ETIII SA Mini</td><td>SUM</td><td>3.75, 3.77</td><td>TS Mini</td></tr>
<tr><td>Hiossen ETIII SA</td><td rowspan="2">SURO</td><td>4.25, 4.65, 4.63, 4.6, 5.1, 5.08, 5.05,</td><td rowspan="2">TS Regular</td></tr>
<tr><td>Hiossen ETIII SA Ultra-Wide</td><td>5.9, 5.92, 5.95, 6.0, 6.8, 6.82</td></tr>
<tr><td>Megagen Anyone Internal (normal thread, deep thread, special length)</td><td>DERA (MAO)</td><td>3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3</td><td>Universal</td></tr>
<tr><td>Megagen AnyRidge Internal (normal ridge, deep ridge)</td><td>MARR</td><td>4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4</td><td>Universal</td></tr>
<tr><td>Megagen MiNi Internal</td><td>MMN</td><td>3.0, 3.4</td><td>MINI</td></tr>
</table>
All digitally designed custom abutments for use with Geo Abutments are to be sent to a GeoMedi Co. Ltd. validated milling center for manufacture.</td></tr>
</table>

<table>
<tr><th colspan="2">Primary Predicate Device</th></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>

Reference Device

K222368
MIST IC
Imagine Milling Technologies, LLC

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.

Table 2. Table of Substantial Equivalence – Technological Characteristics

Features	Subject Device	Primary Predicate Device	Reference Device
	Geo Abutment GeoMedi Co, Ltd.	K182246 MIST IC Imagine Milling Technologies, LLC	K222368 MIST IC Imagine Milling Technologies, LLC
			
Reason for Predicate Device	**Not applicable**	**Abutment designs, materials, manufacturing, sterilization**	**Abutment designs, materials, manufacturing, sterilization**
Designs			
Abutment Designs	CAD/CAM Titanium Base (Multibase) CAD/CAM Titanium Blank (CMFit)	CAD-CAM Titanium Base (L-LINK, S-LINK) CAD-CAM Titanium Blank (PREFIT)	CAD-CAM Titanium Base (L-LINK) CAD-CAM Titanium Blank (PREFIT)
Restoration	Single-Unit Multi-Unit	Single-Unit Multi-Unit	Single-Unit Multi-Unit
Prosthesis Attachment	Cement-retained	Cement-retained	Cement-retained
Base Abutment Design Parameters for Zirconia Superstructure			
Minimum wall thickness, mm	0.5	0.5	0.5
Minimum cementable post height for single-unit restoration, mm	4.0	4.0	4.0
Minimum gingival height, mm	0 (bases have minimum gingival height of 0.5 mm)	0 (all bases have minimum gingival height of 0.6 mm)	0 (all bases have minimum gingival height of 0.5 mm)
Maximum gingival height, mm	5.0	5.0	5.0
Angulation	0° (straight only)	Up to 20°	Up to 20°

Features	Subject Device	Primary Predicate Device	Reference Device
	Geo Abutment GeoMedi Co, Ltd.	K182246 MIST IC Imagine Milling Technologies, LLC	K222368 MIST IC Imagine Milling Technologies, LLC
Required 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	3M ESPE RelyX Unicem bonding cement, cleared in K022476 as RelyX RMGIP
Blank Abutment – Finished Design Parameters			
Minimum wall thickness, mm	0.65	0.5	0.5
Minimum cementable post height for single-unit restoration, mm	4.0	4.0	4.0
Minimum gingival height, mm	0.5	*Not provided in 510(k) Summary*	0.5
Maximum gingival height, mm	5.0	5.0	5.0
Angulation	Up to 30°	Up to 30°	Up to 30°
Abutment/ Implant Interface	Internal	Internal	Internal
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)
Screws	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)
Coating on Titanium Base	Titanium nitride (TiN)	Titanium nitride (TiN)	Titanium nitride (TiN)
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