April 16, 2019

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

Re: K182246
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: January 15, 2019
Received: January 16, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K182246

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:

Keystone Dental Implant Line	Platform Diameter (mm)	Body Diameter (mm)
Genesis	3.8, 4.5, 5.5, 6.5	3.8, 4.5, 5.5, 6.5
PrimaConnex® 1.0 (Straight)	3.5, 4.1, 5.0	3.3, 4.0, 5.0
PrimaConnex® 1.0 (Tapered)	3.5, 4.1, 5.0	3.5, 4.1, 5.0

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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
K182246
Imagine Milling Technologies, LLC
MIST IC

April 16, 2019

ADMINISTRATIVE INFORMATION

Manufacturer Name	Imagine Milling Technologies, LLC 14225-E Sullyfield Circle Chantilly, VA 20151 Telephone: +1 (703) 725-6015
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
Classification Name	Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3630, Class II
Product Code	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate
K170588, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K151621, BioHorizons CAD/CAM Abutments, BioHorizons Implant Systems, Inc.
K092351, Low Profile Abutment, Biomet *3i*, Inc.
K101545, Genesis Implant System, Keystone Dental, Inc.
K051614, PrimaConnex™ Internal Connection Implant System, Lifecore Biomedical, Incorporated

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:

Keystone Dental Implant Line	Platform Diameter (mm)	Body Diameter (mm)
Genesis	3.8, 4.5, 5.5, 6.5	3.8, 4.5, 5.5, 6.5
PrimaConnex® 1.0 (Straight)	3.5, 4.1, 5.0	3.3, 4.0, 5.0
PrimaConnex® 1.0 (Tapered)	3.5, 4.1, 5.0	3.5, 4.1, 5.0

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.

DEVICE DESCRIPTION

MIST IC abutments include three abutment designs, MIST IC L-LINK, MIST IC S-LINK, and MIST IC PREFIT, having connections compatible with three Keystone Dental implant systems. Subject device abutments are provided in three interface connection diameters (SD (3.5 mm), RD (4.1 mm) and WD (5.0 mm)). All subject device abutments have the same connection type to the compatible Keystone Dental implants cleared in K101545 and K051614. Corresponding compatible implant platform diameters range from 3.5 mm to 6.5 mm. Corresponding compatible implant body diameters range from 3.3 mm to 6.5 mm. All sizes of the compatible Keystone Dental implants have one of the three interface connection sizes (SD, RD, and WD).

All subject device L-LINK and S-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. MIST IC S-LINK has a cut out in the post to accommodate a restoration with an angled screw channel when clinically necessary. MIST IC PREFIT abutments are titanium cylindrical abutments designed for patient specific abutment fabrication using a CAD/CAM process. All patient-specific abutment fabrication is by prescription on the order of the clinician.

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; maximum gingival height – 5.0 mm; and maximum angle – 20°.

Design parameters for the S-LINK zirconia superstructure are: minimum wall thickness – 0.7 mm; minimum post height for single-unit restoration – 4.0 mm; maximum gingival height – 5.0 mm; and maximum angle – 20°.

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; maximum gingival height – 5.0 mm; and maximum angle – 30°.

All subject device components (abutments and abutment screws) are made of titanium alloy conforming to ASTM F136. Zirconia superstructures for subject device abutments are made of Y-TZP conforming to ISO 13356.

All subject device components are provided non-sterile, and are intended to be end-user sterilized.

PERFORMANCE DATA

Non-clinical testing data submitted, or relied upon to demonstrate substantial equivalence included: sterilization validation according to ISO 17665-1 and ISO 17665-2; biological evaluation according to ISO 10993-1 with cytotoxicity testing conforming to ISO 10993-5 and ISO 10993-12; and static and dynamic compression-bending testing according to ISO 14801.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

The subject device abutments are compatible with PrimaConnex dental implants cleared in the reference device K051614 and with Genesis dental implants cleared in the reference device K101545. The compatibility of the subject device abutments and the corresponding compatible implants is ensured by a contractual agreement and working relationship between Imagine Milling Technologies, LLC and Keystone Dental.

The subject device abutments are substantially equivalent in intended use to DESS Dental Smart Solutions devices in K170588, BioHorizons CAD/CAM devices in K151621, and Low Profile Abutment devices in K092341. All are intended for use with endosseous dental implants in the maxilla and mandible to provide prosthetic support to restore chewing function.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to the primary predicate K170588. Slight differences in language of the subject device and primary predicate device 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 between the IFUS for the subject device and the primary predicate include: the subject device IFUS includes the term “prosthetic device” and the primary predicate device IFUS includes the term “prosthetic restorations”; the subject device IFUS includes the terms “partially or completely edentulous patient” and “single-unit or multi-unit, cement-retained” and the primary predicate IFUS does not. The other minor differences are related to the specific device names, validated milling centers, and the compatible OEM implant lines. None of these minor differences impact safety or effectiveness because the both IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

The subject device (MIST IC L-LINK, MIST IC S-LINK, MIST IC PREFIT), primary predicate device K170588, and reference device K151621 are indicated for use with CAD/CAM technology to fabricate patient-specific abutments prescribed by the clinician. All require that digital files for CAD/CAM fabricated abutments be sent to a validated milling center for manufacture.

The final, finished subject device designs (MIST IC L-LINK and MIST IC PREFIT) are substantially equivalent to the final, finished primary predicate designs K170588 (Ti Base and Pre-Milled Blank) in material, design and function. Both are manufactured from titanium alloy (Ti-6Al-4V), and both base designs require a zirconia superstructure. The subject device differs from the primary predicate K170588 in the prosthesis attachment (subject device cement-retained only), range of platform diameters, abutment angulation (K170588 for straight abutments only), and abutment-implant interface (subject device internal connection only). These differences do not impact safety or effectiveness because they are related to the prosthetic restoration attachment or to the compatible OEM implant designs. The difference in angulation is supported by the reference device K151621.

The final, finished design of the subject device MIST IC PREFIT is substantially equivalent to the final, finished design of the K151621 Titanium Abutment Blank 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 MIST IC PREFIT and the K151621 titanium blank have the same range of angulation (up to 30°). The differences between the subject device and the K151621 titanium blank (range of platform diameters and implant interface) do not impact safety or effectiveness because these differences are related to the compatible OEM implant designs.

MIST IC S-LINK is substantially equivalent to the K151621 BioHorizons CAD/CAM Abutment Titanium Base in material, design and function. Both are for cement-retained, single-unit or multi-unit restorations. Both are manufactured from titanium alloy (Ti 6Al 4V) with a TiN surface treatment. MIST IC S-LINK, prior to zirconia superstructure bonding, has a post height of 3.8 mm with a cut-out to accommodate a diagonal screw channel. BioHorizons CAD/CAM Abutment Titanium Base has a 4.0 mm post height with a cut out to accommodate a diagonal screw channel. The subject device MIST IC S-LINK and the K151621 Abutment Titanium Base have the same range of angulation (up to 20°). The differences between the subject device and the K151621 Abutment Titanium Base (range of platform diameters and implant interface) do not impact safety or effectiveness because these differences are related to the compatible OEM implant designs.

MIST IC S-LINK is substantially equivalent to Low Profile Abutment (K092341) for use in single unit and multi-unit restorations. When used with the bonded zirconia superstructure, MIST IC S-LINK is intended for single-unit or multi-unit restorations. When used with a direct restoration the MIST IC S-LINK is intended for a multi-unit prosthesis. The predicate Low Profile Abutment has a post height of 2.2 mm to accommodate multi-unit prostheses. Both MIST IC S LINK and Low Profile Abutment can be used with a superstructure to create a 4 mm post height appropriate for a single unit restoration. The subject device differs from the reference device K092341 because K092341 is provided in final form and is not to be customized; this difference does not impact safety or effectiveness. The minimum post height for the final, finished subject device MIST IC S-LINK (with superstructure) is 4.0 mm for single-unit restorations.

The primary predicate K170588 Ti Base is for use with straight superstructure only (0°). The reference device K151621 Abutment Titanium Base is for use with a superstructure up to 20°; the reference device K092341 abutments are for use with a superstructure up to 30°. Except for the angulation, the exact limits of fabrication of the titanium base superstructures from K170588, K151621, and of K092341 are not in the respective 510(k) Summaries. The differences in the design limits among the superstructures for the subject device S-LINK and L-LINK, K170588, K151621, and K092341 are mitigated by ISO 14801 performance testing of the subject device constructs.

The reference devices K051614 and K101545 are for the dental implants that are compatible with the subject device abutments.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and angle of the abutments. The subject and predicate devices are packaged in similar materials and are to be sterilized using similar methods.

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

Comparison of Indications for Use Statements

<table>
<tr><th></th><th>Indications for Use</th></tr>
<tr><td>Subject Device

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><td>Keystone Dental Implant Line</td><td>Platform Diameter (mm)</td><td>Body Diameter (mm)</td></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>
<tr><td>Predicate Device

K170588

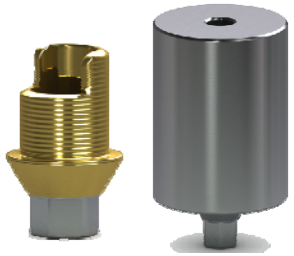
DESS Dental Smart Solutions

Terrats Medical SL</td><td>DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.
All digitally designed custom abutments for use with TiBase or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems

<table>
<tr><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>3i Certain®</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>3i OSSEOTITE®</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>OsseoSpeed™</td><td>3.5, 4.0, 5.0</td><td>3.5/4.0, 4.5/5.0</td></tr>
<tr><td>FRIADENT XiVE</td><td>3.4, 3.8, 4.5</td><td>3.4, 3.8, 4.5</td></tr>
<tr><td>NobelActive®</td><td>3.5, 4.3, 5.0</td><td>NP, RP</td></tr>
<tr><td>NobelReplace Conical</td><td>3.5, 4.3, 5.0</td><td>NP, RP</td></tr>
<tr><td>Nobel Replace Trilobe</td><td>3.5, 4.3, 5.0</td><td>NP, RP, WP</td></tr>
<tr><td>Brånemark</td><td>3.5, 3.75/4.0, 5.0</td><td>NP, RP, WP</td></tr>
<tr><td>Straumann® Bone Level</td><td>3.3, 4.1, 4.8</td><td>NC, RC</td></tr>
<tr><td>Straumann® Tissue Level</td><td>3.3, 4.1, 4.8</td><td>RN, WN</td></tr>
<tr><td>Tapered Screw-Vent®</td><td>3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
</table>
</td></tr>
</table>

Comparison of Technological Characteristics

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	K182246 MIST IC Imagine Milling Technologies, LLC	K170588 DESS Dental Smart Solutions Terrats Medical SL	K151621 BioHorizons CAD/CAM Abutments BioHorizons Implant Systems, Inc.	K092341 Low Profile Abutment Biomet *3i*, Inc.
				
Reason for Predicate	Not applicable	IFU Statement, Titanium Base, Titanium Blank	Cut-out Titanium Base, Titanium Blank, Angled Abutments, Titanium Nitride	Short single-unit post height
Design				
Abutment Design	CAD/CAM Titanium Base CAD/CAM Blank	CAD/CAM Titanium Base CAD/CAM Blank	CAD/CAM Titanium Base CAD/CAM Blank	Titanium Abutment
Prosthesis Attachment	Cement-retained	Cement-retained Screw-retained	Cement-retained	Screw-retained
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit
Abutment/Implant Platform Diameter (mm)	3.5 – 5.0	3.4 – 6.5	3.0 – 5.7	3.4 – 5.0
Abutment Angle	Titanium Base = Up to 20° Blank = Up to 30°	0°	Titanium Base = Up to 20° Blank = Up to 30°	0°, 17°, 30°
Abutment/ Implant Interface	Internal	Internal/External	Internal	Internal and External
Material				
Abutment	Titanium Alloy, Zirconia	Titanium Alloy, Zirconia	Titanium Alloy, Zirconia	Titanium Alloy
Screw	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy