January 28, 2019

MIS Implants Technologies Ltd.
Arbel Shezaf
RA Coordinator
P.O. Box 7
Bar Lev Industrial Park, 2015600
ISRAEL

Re: K182228
Trade/Device Name: MIS LOCKiT Abutments System, OT-Equators and Ball Attachments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 3, 2019
Received: January 3, 2019

Dear Arbel Shezaf:

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,

Andrew I. Steen -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182228

Device Name
MIS LOCKiT Abutments System, OT-Equators and Ball Attachments

Indications for Use *(Describe)*

MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.

Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.

The long MIS (18 & 20 mm) implants can be used in a tilted manner.

MIS short implants are to be used only with straight abutments.

M4 short implants are indicated for delayed loading 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.

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Implants Technologies Ltd.

510(k) Summary

1. Submitter

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Contact: Arbel Shezaf
Date Prepared: January 22, 2019

2. US Agent: Motti Weisman - VP Marketing

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Phone: (201) 797-9144
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3. Device Identification

Trade/Proprietary Name:	MIS LOCKiT Abutments System, OT-Equators and Ball Attachments
Common/Usual Name:	Dental implant abutment
Classification Name:	Endosseous dental implant abutment
Regulation Number:	872.3630
Product Code:	NHA
Device Class:	Class II
Classification Panel:	Dental Devices Panel

4. Predicate Device(s)

Primary predicate device:

- MIS Conical Connection Equators cleared under K163349

Reference devices:

- Zest Locator® Implants Attachments cleared under K072878
- MIS Conical Connection Equators cleared under K172505
- MIS Internal Hex Connection Equators cleared under K180282
- MIS CONNECT Conical Connection Abutment cleared under K173326

- MIS Conical Connection Implants cleared under K112162
- MIS Dental Implant System cleared under K040807

5. Device Description

a. MIS LOCKiT Abutments System

MIS LOCKiT abutments system contains titanium abutments coated with titanium nitride (TiN). MIS LOCKiT abutments system is intended to be used in completely edentulous jaws and connects to an overdenture to allow its insertion and removal.

MIS LOCKiT abutments connect directly to the implant by their threading. MIS LOCKiT abutments are available in three different platforms (narrow platform (NP), standard platform (SP) and wide platform (WP)) and two connection types (conical connection and internal hex connection). LOCKiT abutments system contains straight abutments only.

MIS LOCKiT abutments are provided in the following gingival heights:

- Narrow platform: 1, 2, 3, 4, 5 mm
- Standard platform: 1, 2, 3, 4, 5 mm
- Wide platform: 1, 3, 5 mm

MIS LOCKiT internal hex connection abutments are compatible with MIS internal hex implants cleared under K040807 and K180282 (M4, LANCE and SEVEN Systems).

MIS LOCKiT conical connection abutments are compatible with MIS implants cleared under K112162, K163349 and K172505 (C1 and V3 Systems).

b. OT-Equators and Ball Attachments

Ball Attachments and OT-Equators are used to connect to an overdenture bar to allow its insertion and removal. They are connected directly to the implant by their distal threading, and are mostly used in complete edentulous jaws. The main difference between them is that ball attachments have a higher profile and ball shaped head, while the OT-equators have a lower profile and a truncated head. Both are made from Titanium 6Al-4V ELI and feature a Titanium Nitride (TiN) coating for increased resistance to wear.

Internal hex OT-Equators and Ball Attachments are available in three different platforms (narrow platform (NP), standard platform (SP) and wide platform (WP) and are available in the following gingival heights:

- Narrow platform: 1, 2, 3, 4, 5 mm
- Standard platform: 1, 2, 3, 4, 5 mm
- Wide platform: 1, 3, 5 mm

MIS Internal hex OT-Equators and Ball Attachments are compatible with MIS internal hex implants cleared under K040807 and K180282 (M4, LANCE and SEVEN Systems).

6. Indications for Use

MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.
When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.
Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.
The long MIS (18 & 20 mm) implants can be used in a tilted manner.
MIS short implants are to be used only with straight abutments.
M4 short implants are indicated for delayed loading only.

7. Substantial Equivalence Discussion

a. MIS LOCKiT Abutments System:

The predicate device for the Conical Connection MIS LOCKiT abutments is MIS Conical Connection Equators cleared under K163349 and K172505, while the predicate device for the Internal Hex Connection MIS LOCKiT abutments is the MIS Internal Hex Connection Equators recently cleared under K180282. Two reference devices for MIS LOCKiT abutments are also included, specifically, the Zest Locator® Implants Attachments (K072878) and MIS CONNECT Conical Connection Abutment (K173326). All devices have identical intended use. The indications listed for the LOCKiT are identical to the indications for MIS Equators and do not meaningfully differ from the Zest Locator.
All abutments are made from titanium or its alloy, and undergo TiN coating. In regards to the distal geometry, the conical implant connection geometry for the Conical Connection MIS LOCKiT is identical to the MIS Conical Connection Equators while the internal hex connection is equivalent to MIS Internal Hex Connection Equators. The subject and the predicate devices are available in the same gingival heights - 1, 2, 3, 4, 5 mm (both conical and internal hex connection, narrow and standard platform) and 1, 3, 5 mm (both conical and internal hex connections, wide platform).
MIS CONNECT Conical Connection Abutments and Zest Locator® Implants Attachments were chosen as a reference device in terms of fatigue limit. MIS LOCKiT abutment (internal hexagon connection, NP and SP) were tested in order to determine the fatigue limit value of an implant-abutment assembly. The endurance limit for the LOCKiT assembly was compared with the corresponding worst case for CONNECT and Zest Locator® systems.

MIS Implants Technologies Ltd.

Trade Name	MIS LOCKiT Abutments (conical and internal hex connection) New device	MIS Equators (conical and internal hex connection) Primary predicate	MIS CONNECT Conical Connection Abutments Reference device (fatigue strength)	ZEST Locator ® Implants Attachments Reference device (proximal connection)
510(k) Number	Subject	**Conical Connection:** K163349, K172505 **Internal Hex Connection:** K180282	K173326	K072878
Manufacturer	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.	Zest Anchors LLC.
Device Class	Class II	Class II	Class II	Class II
Product Code(s)	NHA	NHA	NHA	NHA
Regulation Description	Endosseous dental implant abutment	Endosseous dental implant abutment	Endosseous dental implant abutment	Endosseous dental implant abutment
Regulation Number	872.3630	872.3630	872.3630	872.3630
Intended use:	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. Intended for fully edentulous jaw retaining a tissue supported overdenture.	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. Intended for fully edentulous jaw retaining a tissue supported overdenture.	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. Intended for fully edentulous jaw retaining a tissue supported overdenture.	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. Intended for fully edentulous jaw retaining a tissue supported overdenture.
Indications for use:	MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is	MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	MIS Dental Implant Systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	The Locator® Implant Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.

Trade Name	MIS LOCKiT Abutments (conical and internal hex connection) New device	MIS Equators (conical and internal hex connection) Primary predicate	MIS CONNECT Conical Connection Abutments Reference device (fatigue strength)	ZEST Locator ® Implants Attachments Reference device (proximal connection)
	applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.	When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (″3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. **For the internal hex connection MIS Equators,** there is a following addition to the indications for use: The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for	When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	

Trade Name	MIS LOCKiT Abutments (conical and internal hex connection) New device	MIS Equators (conical and internal hex connection) Primary predicate	MIS CONNECT Conical Connection Abutments Reference device (fatigue strength)	ZEST Locator ® Implants Attachments Reference device (proximal connection)
		delayed loading only.		
Material(s)	Ti 6Al 4V ELI	Ti 6Al 4V ELI	Ti 6Al 4V ELI	Ti 6Al 4V ELI
Surface Treatment	TiN coating, SP and WP also color anodized	TiN coating, SP and WP also color anodized	Anodized	TiN coating
Connection of the Abutment to the Implant	• Conical Connection without indexes • Internal Hex Connection	• Conical Connection without indexes • Internal Hex Connection	• Conical Connection without indexes	• Conical Connection without indexes • Internal Hex Connection
Gingival height	NP / SP (both connections): 1, 2,3, 4, 5 mm WP (both connections): 1, 3, 5 mm	NP / SP: 1, 2, 3, 4, 5 mm WP: 1, 3, 5 mm	NP: 2, 3 mm SP: 1.5, 2, 3, 4 mm WP: 1.5, 2, 3, 4 mm	NP / SP (conical connection): 1, 2, 3, 4, 5 mm NP / SP / WP (internal hex connection): 0, 1, 2, 3, 4, 5, 6 mm
Platform	NP / SP / WP (both connections)	NP / SP / WP	NP / SP / WP	Conical Connection: NP / SP Internal Hex Connection: NP / SP / WP
Abutment Angulation	0°	0°	0°	0°
Maximum Implant Angulation Allowed	20 degrees of divergence (40 degrees between implants)	**Conical Connection:** 15 degrees of divergence (30 degrees between implants) **Internal Hex Connection:** No angulation is allowed	20 degrees of divergence (30 degrees between implants)	20 degrees of divergence (40 degrees between implants)
Sterilization Method	Product provided non-sterile	Product provided non-sterile	Product provided non-sterile	Product provided non-sterile

b. OT-Equators and Ball Attachments

OT-Equators and Ball Attachments were cleared under K180282. No changes have been made since the clearance, as shown in the following table.

They were cleared with the following instructions:

"OT-Equators and straight Ball Attachments are not to be used with implants placed at an angle."

Due to fatigue tests provided in this submission, the instruction is changed to:

"OT-Equators and straight Ball Attachments allow a maximum 30 divergence between two implant constructs, with each implant/abutment construct having no more than 15°correction."

Trade Name	**MIS internal hex OT-Equators and Ball Attachments**	**MIS internal hex OT-Equators and Ball Attachments**
510(k) Number	Subject	K180282
Manufacturer	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd
Device Class	Class II	Class II
Product Code(s)	NHA	NHA
Regulation Description	Endosseous dental implant abutment	Endosseous dental implant abutment
Regulation Number	872.3630	872.3630
Intended use:	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. For fully edentulous jaw retaining a tissue-supported overdenture.	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. For fully edentulous jaw retaining a tissue-supported overdenture.
Indications for use:	MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only	MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only
Instruction for use	OT-Equators and straight Ball Attachments allow a maximum 30° divergence between two implant constructs, with each implant/ abutment construct having no more than 15° correction	OT-Equators and straight Ball Attachments are not to be used with implants placed at an angle.
Material(s)	Ti 6Al 4V ELI per ASTM F136	Ti 6Al 4V ELI per ASTM F136
Surface Treatment	TiN coating after machined	TiN coating after machined

Trade Name	MIS internal hex OT-Equators and Ball Attachments	MIS internal hex OT-Equators and Ball Attachments
Connection Type	Internal hexagon	Internal hexagon
Platform	NP, SP, WP	NP, SP, WP
Abutment angulation	0°	0°
Maximum Implant Angulation Allowed	15 degrees of divergence (30 degrees between implants)	0 degrees of divergence
Abutment Diameters	NP: ball 4.0, equator 4.1 mm SP: ball & equator 4.1 mm WP: ball & equator 5.0 mm	NP: ball 4.0, equator 4.1 mm SP: ball & equator 4.1 mm WP: ball & equator 5.0 mm
Gingival height	1, 2, 3, 4, 5 mm	1, 2, 3, 4, 5 mm
Sterilization Method	Product provided non sterile	Product provided non sterile

8. Non-Clinical Performance Data

As part of demonstrating the substantial equivalence of the MIS LOCKiT Abutments System, OT-Equators and Ball Attachments to the predicate devices listed in this 510(k) submission, MIS Implants Technologies completed a number of non-clinical performance tests:

- Biocompatibility - The subject device is manufactured using identical manufacturing methods, in the same manufacturing facility, and using the same raw material as the previously cleared predicate, K040807. The subject device is packaged using identical materials and processing as the predicate. Finally the subject device has the same intended use, patient contact duration and type as the predicate. For these reasons, biocompatibility testing was not required to support the substantial equivalence of the subject device.
- Mechanical testing –
    - Fatigue testing of MIS Internal Hex LOCKiT abutments was conducted in accordance with ISO 14801:2016. The worst case implants and abutments chosen for the tests were the narrowest implants loaded with the abutments which have the maximum gingival height for both narrow and standard platforms. The test articles were able to withstand 5,000,000 cycles without failure at a substantially equivalent load to the cited predicates. The fatigue test conducted on the standard platform worst case implant-abutment assembly supports the wide platform implants as the SP is a worst case in terms of diameter and wall thickness, and both SP and WP implants are made of the same material.
    - Mechanical performance of MIS Conical Connection LOCKiT abutments is supported by fatigue testing that was conducted on MIS conical connection CONNECT abutments (cleared

under K173326) which represent a worst-case in terms of mechanical properties due to geometric design.

- Mechanical performance of MIS internal hex OT-Equators and Ball Attachments is supported by the fatigue testing that was conducted on MIS Internal Hex LOCKiT abutments, which are a worst case in terms of mechanical strength as they have a narrower emergence profile than the OT-Equators and Ball Attachments.

- Sterilization testing (steam sterilization by the user): The steam sterilization parameters were validated according to ANSI/AAMI/ISO 17665-1:2006 and ANSI/AAMI/ISO 17665-2:2009 for two methods: gravity displacement steam sterilization and pre vacuum steam sterilization.
- Disinfection validation: the disinfection procedure was validated in accordance with ANSI/AAMI/ISO 11737-1:2006 (R) 2011, AAMI TIR 30:2011 and AAMI TIR 12:2010 by demonstrating a reduction of at least 10^6 of the microbiological challenge.

9. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

10. Summary

The comparison between the subject device and the predicate devices has shown that the indications for use, principles of operation, technological characteristics and materials were similar, and that the differences did not raise new safety and effectiveness issues. Furthermore, performance testing showed that the predicate device is at least equivalent to the predicates by means of performance.

11. Conclusions

MIS LOCKiT Abutments System, OT-Equators and Ball Attachments have the same intended use, incorporate the same fundamental technology, and have similar indications for use as the predicate. Test data to verify the performance of the MIS LOCKiT Abutments System, OT-Equators and Ball Attachments has been provided including dynamic fatigue, pull-out tests and sterilization validation. The results of this testing, combined with the design and intended use comparison with the predicate device, support substantial equivalence.