June 22, 2018

MIS Implants Technologies Ltd.
% Randy Prebula
Partner
Hogan Lovells US LLP
555 13th Street, NW
Washington, District of Columbia 20004

Re: K180282
Trade/Device Name: MIS Internal Hex Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 29, 2018
Received: May 29, 2018

Dear Randy Prebula:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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)*
K180282

Device Name
MIS Internal Hex Dental Implant System

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.

K180282 510(k) Summary

1. Submitter

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Contact: Arbel Shezaf
Date Prepared: 21 June 2018

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3. Device Identification

Trade/Proprietary Name:	MIS Internal Hex Dental Implant System
Common/Usual Name:	Dental Implant
Classification Name:	Endosseous dental implant
Regulation Number:	872.3640;
Product Code:	DZE, NHA
Device Class:	Class II
Classification Panel:	Dental Devices Panel

4. Predicate Device(s)

Primary predicate device: MIS Dental Implant System cleared under 510(k) K040807.
Reference devices:

- MIS Short Implants K103089
- Xive S plus Dental Implant System K073075
- MIS V3 Conical Connection Dental implant System K163349
- 3i OSSEOTITE Certain Dental Implants K063341
- K160828 Dentium Implantium & SuperLine Prosthetics

Device Description

The MIS internal hex implant system includes two implant families: **M4** and **SEVEN**. The subject implants system are endosseous dental implants and Endosseous dental implant abutments, manufactured from

titanium TI-6Al-4V ELI. The implants 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 root-shaped, screw-type implants are designed for both two-stage and single stage procedures, with one internal thread for screwed abutment. The two implant families have the same internal hex connection and differ in regards to external geometry. Accordingly, the implants are used with the same abutments.
The implants are self-tapping, root-form with tapered threads and their surface is sand blasted and acid etched. The implants are supplied sterilized by gamma irradiation.

MIS M4 implants are cylindrical and conical shaped, self-tapping, have a V shaped thread design with three spiral channels and a flat, cutting tapered apex.
The MIS M4 Implants are available in the following diameters, platforms and lengths:

- Narrow platform: 3.3 mm diameter: 10mm, 11.5mm, 13mm and 16 mm
- Standard platform: 3. 75 mm diameter: 8mm, 10mm, 11.5mm, 13mm, 16mm, 18mm and 20mm
- Standard platform: 4.2 mm diameter: 6mm, 8mm, 10mm, 11.5mm, 13mm, 16mm, 18mm and 20mm
- Wide platform: 5.0 mm diameter: 6mm, 8mm, 10mm, 11.5mm, 13mm and 16mm
- Wide platform: 6.0 mm diameter: 6mm, 8mm, 10mm, 11.5mm, 13mm

MIS SEVEN implants are conical shaped with a domed apex. Their geometric design includes dual threads, three spiral channels stemming from the apex for self-tapping, micro rings on the implant neck, and a changing thread thickness along the implant. The implants are color coded for platform identification.
The MIS SEVEN Implants are available in the following diameters, platforms and lengths:

- Narrow platform (yellow): 3.3 mm diameter: 10mm, 11.5mm, 13mm and 16 mm
- Standard platform (purple): 3. 75mm diameter: 8mm, 10mm, 11.5mm, 13mm, 16mm, 18mm and 20mm
- Standard platform (purple): 4.2mm diameter: 8mm, 10mm, 11.5mm, 13mm, 16mm, 18mm and 20mm
- Wide platform (green): 5.0mm diameter: 8mm, 10mm, 11.5mm, 13mm and 16mm
- Wide platform(green): 6.0 mm diameter: 8mm, 10mm, 11.5mm, 13mm
- The implants are designed for both two-stage and single stage procedures, with one internal thread for screwed abutment.

The MIS Internal Hex Dental Implant System is a two-piece device to be used in combination with a wide range of abutments provided in order to aid in the prosthetic rehabilitation.

Components:
The MIS Internal Hex Dental Implant System is to be used in combination with variety of the internal hex abutments (cover screws, healing caps, cement- retained abutments, CPK abutments, gold abutments, OT-

Equators & ball attachments, Multi unit abutments and Temporary Ti and Peek Abutments), including up to 30^{o} angulated abutments.

Cover screws and healing caps are premanufactured prosthetic components directly connected to the endosseous dental implants and are indicated as temporary components to allow healing of the soft tissue. They are made of TI 6AL 4V ELI, and supplied sterile to the user, for single use.

Cement- Retained Abutments are premanufactured dental implant abutments directly connected to the endosseous dental implant by a prosthetic screw, which is supplied with the abutments. Cement retained abutments are available straight or angulated, in different heights and diameters to accommodate the patients specific needs. They are available in 0, 10 or 20 degrees angulation in narrow platform, 0, 15 or 25 degrees angulation in standard platform and 0 or 15 degrees angulation for wide platform. They are made of TI 6AL 4V ELI, and supplied non sterile, to be steam sterilized by the user according to the labeling, intended for single use.

CPK abutments are premanufactured abutments directly connected to the endosseous dental implant by a prosthetic screw, which is supplied with the abutments. They are cement retained abutments intended to be used in temporary and permanent prosthetic rehabilitation. CPK abutments are straight abutments indicated for 0 degree angulation for straight implantation only. They are sold either on their own, or with additional components for impression taking and prosthetic fabrication. The abutments and prosthetic screw are made of TI 6AL 4V ELI. Their additional components intended for impression taking and casting are made of POM. Plastic healing caps intended to cover the CPK abutment until final restoration placement are made of PEEK. They are supplied non sterile, to be steam sterilized by the user according to the labeling, and intended for single use.

Gold Plastic abutments are pre-manufactured prosthetic abutments directly connected to the endosseous dental implant intended for permanent restoration, for either single or multiple tooth screw retained restorations. The lower part of the abutment which connects directly to the implant is made of gold AU, and the upper part is made of plastic (POM). The plastic part is burned out for casting with precious metals.. The abutment is connected to the implant by a prosthetic screw, supplied with the abutment, and made of TI 6AL 4V ELI. Gold abutments are straight abutments intended for 0 degree angulation for straight implantation only. The abutments are supplied non sterile, to be steam sterilized by the user according to the labeling, and intended for single use.

*Multi-Unit abutment*s are premanufactured dental implant abutments directly connected to the endosseous dental implant. They are intended for use in a completely edentulous jaw when screw retained prosthetis is preferred, for anchoring a fixed overdenture. Multi-units are available in 0 degrees for narrow platform, and in 0, 17 or 30 degrees for standard and wide platforms. The straight multi units' lower part is threaded and tightened directly to the implant, while the angulated multi-unit is connected to the implant by a prosthetic screw, supplied with the multi-unit and made of TI 6AL 4V ELI. The overdenture is connected to the multi-unit by a screw. All multi units are made of TI 6AL 4V ELI. They are supplied sterile and intended for single use.

OT-Equators & Ball Attachments are premanufactured dental implant abutments directly connected to the endosseous dental implant by their lower threaded part, and are mostly used in completely edentulous jaws to connect to an overdenture bar to allow its insertion and removal. Ball attachments have a higher profile and ball shaped head, while the OT equators have a lower profile and a truncated head. Ball attachments are available straight for narrow and wide platforms, and in 0, 15 or 25 degrees for standard platform. OT Equators are available straight only. Both are made from TI 6AL 4V ELI, feature a Titanium Nitride (TiN) coating and are supplied with small-scale metal housing and replaceable nylon caps, offering various retention levels. The abutments are supplied non sterile, to be steam sterilized by the user according to the labeling and intended for single use.

*Temporary abutment*s are premanufactured dental implant abutments directly connected to the endosseous dental implant, intended for use as an aid in temporary prosthetic rehabilitation. They are straight abutments. They are available in TI 6AL 4V ELI and in natural PEEK. Both are attached to the implant by a prosthetic screw made from TI 6AL 4V ELI, supplied with the abutments, and are intended to be used for up to 6 months, and then replaced by permanent abutments. The post height is adjusted by the doctor to the appropriate height according to the intended restoration, as directed in the instructions for use supplied with the abutments. The abutments are supplied non sterile, to be steam sterilized by the user according to the labeling and intended for single use.

There are two types of emergence profiles among the abutments, concave or straight emergence profile.

5. 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. .

6. Substantial Equivalence Discussion

The Indications for Use statement for the subject device is not identical to the predicate device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices are

intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function, in partially or fully edentulous patients.

a. **MIS SEVEN and M4 Internal hex Standard and Wide Platform Implants:** The predicate device for the subject MIS SEVEN and M4 Internal hex standard and wide platform implants is MIS Lance Internal hex Implant cleared under K040807. Predicate and subject devices have the same intended use and similar indications, although the subject device mentions indications for narrow implants and for long implants as well, which the predicate device does not contain as it does not have a narrow platform or long implants. Subject and predicate devices all have the exact same internal hex connection and internal geometry per platform. They have the same following diameters: 3.75, 4.20 and 5.0 mm diameters, with an additional 6.0 mm diameter for the subject implants. The length range of the predicate device is 10 -16 mm while the subject devices have an additional 8 mm length. They all undergo the same surface treatment that was cleared under K040807, with additional anodizing in the internal hex connection of the SEVEN implants. Although there are minor differences in threading, apex, body design and neck design, these differences are common in endosseous implants and do not raise different safety or efficacy questions. Fatigue testing per ISO 14801:2016 assessed the impact of these differences and demonstrates at least equivalent performance.

Table 1 – Comparison of Implant Characteristics – M4 and SEVEN Standard and Wide Platform implants and predicate

Trade Name	MIS SEVEN Internal Hex Implants standard & wide platforms	MIS M4 Internal Hex Implants standard & wide platforms	MIS Dental Implant System – Lance Internal Hex Implants
510(k) Number	Subject	Subject	K040807
Manufacturer	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.
Device Class	Class II	Class II	Class II
Product Code(s)	DZE	DZE	DZE
Regulation Description	Endosseous dental implant	Endosseous dental implant	Endosseous dental implant
Regulation Number	872.3640	872.3640	872.3640
Intended use:	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.

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.	The MIS dental implant system is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.
Implant Material(s)	Titanium 6Al-4V ELI per ASTM F136	Titanium 6Al-4V ELI per ASTM F136	Titanium grade 4
Surface Treatment	Anodized, sand blasted and acid etched	Sand blasted and acid etched	Sand blasted and acid etched
Connection Type	Internal hexagon	Internal hexagon	Internal hexagon
Body design	Tapered, conical shape, threaded	Cylindrical upper half and conical lower half design, threaded	Tapered, conical shape, threaded
Neck Design	Cylindrical, with micro-rings	Cylindrical	Cylindrical
Apex	Domed	Flat	Domed
Thread	Dual	Dual	Triple
Type of implant	Bone level implant	Bone level implant	Bone level implant
Implant Diameters (mm)	3.75, 4.20, 5.0, 6.0	3.75, 4.20, 5.0, 6.0	3.75, 4.20, 5.0
Implant Lengths (mm)	8, 10, 11.5, 13, 16	8, 10, 11.5, 13, 16	10, 11.5, 13, 16
Sterilization Method	Radiation	Radiation	Radiation

b. MIS SEVEN and M4 Internal Hex Narrow Platform Implants: The predicate device for the subject MIS SEVEN and M4 Internal hex narrow platform implants is Xive S plus dental implant. Predicate and subject devices have the same intended use and similar indications for use, although the predicate device is not limited to a specific region of the mouth, and may be splinted when using multiple implants, while the subject implants are limited for use in the mandibular central, lateral incisor and maxillary lateral incisor regions and must be splinted when using two or more implants. Predicate and subject devices all feature an internal hex connection. The subject implants have a 3.30 mm diameter, while the predicate has a 3.40 mm diameter. The length range of the subject devices is 10 -16 mm and are within the range of the predicate (9.5 – 18 mm). Predicate and subject devices are sand blasted and acid etched. The subject devices are made from TI 6Al-4V ELI while the predicate is made from CP Titanium grade 2. There are minor differences in diameter, threading, body design, apex and neck design, and these differences are common in endosseous implants and do not raise different safety or efficacy questions. Fatigue testing per ISO 14801:2016 assessed the impact of these differences and demonstrates at least equivalent performance.

Table 2 – Comparison of Implant Characteristics – M4 and SEVEN narrow platform implants and predicate

Trade Name	MIS SEVEN Internal hex narrow platform Implants	MIS M4 Internal hex narrow platform Implants	Xive S plus Dental Implant System
510(k) Number	Subject	Subject	K073075
Manufacturer	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.	Dentsply Implants
Device Class	Class II	Class II	Class II
Product Code(s)	DZE	DZE	DZE
Regulation Description	Endosseous dental implant	Endosseous dental implant	Endosseous dental implant
Regulation Number	872.3640	872.3640	872.3640
Intended use:	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.
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.	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.	The FRIADENT Implant systems (FRIALIT® plus Dental Implant System, XiVE® S plus Dental Implant System, XiVE® TG plus Dental Implant System, ANKYLOS® plus Dental Implant System) are for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The FRIADENT Implant Systems are intended for immediate placement

	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..	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..	and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.
Implant Material(s)	Titanium 6Al-4V ELI per ASTM F136	Titanium 6Al-4V ELI per ASTM F136	CP Titanium grade 2
Surface Treatment	Anodized, sand blasted and acid etched	Sand blasted and acid etched	FRIADENT plus implant surface: sand blasted and acid etched
Connection Type	Internal hexagon	Internal hexagon	Internal hexagon
Body design	Tapered, conical shape, threaded	Cylindrical upper half and conical lower half design, threaded	Cylindrical
Neck Design	Cylindrical, with micro-rings	Cylindrical	Conical
Apex	Domed	Flat	Domed
Thread	Dual	Dual	Dual
Type of implant	Bone level implant	Bone level implant	Bone level implant
Implant Diameters	Ø 3.30 mm	Ø 3.30 mm	Ø3.40 mm
Implant Lengths	10, 11.5, 13, 16 mm	10, 11.5, 13, 16 mm	9.5, 11, 13, 15, 18 mm
Sterilization Method	Radiation	Radiation	Radiation

c. **MIS M4 internal hex Short Implants:** The predicate device for MIS M4 Internal hex Short Implants is MIS SEVEN Short Implants cleared under K103089. Both devices have the same intended use and similar indications, although the subject device mentions indications for narrow implants and for long implants as well, which the predicate device does not contain as it does not have a narrow platform or long implants. The subject and predicate devices have the same length of 6 mm. They are available in the same diameters: 4.20, 5.0 and 6.0 mm. Both are made from the same Ti alloy 6Al 4V ELI (ASTM F136). They undergo the same surface treatment that was cleared under K103089. Their internal hex connection is the exact same and they differ in their external design only. Their differences in threading, neck design, body design and apex were assessed and based

on the assessment it was concluded that no additional fatigue testing was needed to establish substantial equivalence, since they are not a new worst case and that these differences do not raise different safety or efficacy questions.

Table 3 – Comparison of Implant Characteristics – M4 short implants and predicate

Trade Name	MIS M4 Internal Hex Short Implants	MIS SEVEN Internal hex Short Implants
510(k) Number	Subject	K103089
Manufacturer	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.
Device Class	Class II	Class II
Product Code(s)	DZE	DZE
Regulation Description	Endosseous dental implant	Endosseous dental implant
Regulation Number	872.3640	872.3640
Intended use:	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.
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 implants 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 a patient's chewing function. When o one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. MIS short implants are to be used only with straight abutments.
Implant Material	Titanium 6Al 4V ELI per ASTM F136	Titanium 6Al 4V ELI per ASTM F136
Body design	Cylindrical upper half and conical lower half design, threaded	Tapered, conical shape, threaded
Neck Design	Cylindrical	Cylindrical, with micro-rings
Apex	Flat	Domed
Thread	Dual	Dual

Connection Type	Internal hexagon	Internal hexagon
Surface Treatment	Sand blasted and acid etched	Sand blasted, acid etched and anodized.
Type of implant	Bone level implant	Bone level implant
Implant Diameters	Ø 4.20, 5.0, 6.0 mm	Ø 4.20, 5.0, 6.0 mm
Implant Lengths	6 mm	6 mm
Sterilization Method	Radiation	Radiation

d. **MIS SEVEN and M4 long implants:** The predicate device for the subject SEVEN and M4 long implants is BIOMET 3i Osseotite Certain dental implant. Both subject and predicate devices have the same intended use and similar indications, although the subject implants are also indicated for use in a tilted manner. The predicate implants do not mention this Indication. The predicate and subject devices have the same lengths of 18 and 20 mm. They have an internal hex connection and acid etched surface treatment. The predicate 18 mm long implants are available in 3.25 and 4.0 mm diameters, while the subject implant of the same length is available in diameters of 3.75 and 4.2 mm. The predicate 20 mm length implants are available in 4.0 mm diameter, while the subject implants of 20 mm length are available in diameters of 3.75 and 4.2 mm. Even though the predicate implants are 0.25 mm wider than the subject 3.75 implants, it is MIS's opinion that this does not pose a new risk. Supporting this is the fact that MIS 16 mm length implants which were tested for fatigue have the same wall thickness at potting level as the 20 mm long implants.

Table 4 – Comparison of Implant Characteristics – M4 and SEVEN long implants and predicate

Trade Name	MIS SEVEN Internal hex long implants	MIS M4 Internal hex long implants	BIOMET 3i OSSEOTITE Certain Dental Implants
510(k) Number	Subject	Subject	K063341
Manufacturer	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.	Implant Innovations Inc.
Device Class	Class II	Class II	Class II
Product Code(s)	DZE	DZE	DZE
Regulation Description	Endosseous dental implant	Endosseous dental implant	Endosseous dental implant
Regulation Number	872.3640	872.3640	872.3640
Intended use:	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.

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..	*3i* dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. In addition, when a minimum of 4 implants, > 10mm in length, are placed in the mandible and splinted in the anterior region, immediate loading is indicated.
Implant Material(s)	Titanium 6Al-4V ELI per ASTM F136	Titanium 6Al-4V ELI per ASTM F136	Titanium Alloy
Surface Treatment	Anodized, sand blasted and acid etched	Sand blasted and acid etched	Lower half Acid etched
Connection Type	Internal hexagon	Internal hexagon	Internal hexagon
Body design	Tapered, conical shape, threaded	Cylindrical upper half and conical lower half design, threaded	Cylindrical
Neck Design	Cylindrical, with micro-rings	Cylindrical	Cylindrical
Apex	Domed	Flat	Flat
Thread	Dual	Dual	Dual
Type of implant	Bone level implant	Bone level implant	Bone level implant
Implant Diameters (mm)	18 mm length: 3.75, 4.20 20 mm length: 3.75, 4.20	18 mm length: 3.75, 4.20 20 mm length: 3.75, 4.20	18 mm length: 3.25, 4.0 20 mm length: 4.0
Implant Lengths (mm)	18, 20	18, 20	18., 20
Sterilization Method	Radiation	Radiation	Radiation

e. **Abutments:** Healing caps, cover screws, cement retained abutments, CPK abutments, gold abutments, multi-units, temporary abutments, OT-equators and ball attachments were compared to equivalent MIS internal hex connection abutments, which share the same indications, are made of the same materials, manufactured in the same facility with the same manufacturing conditions and undergo the same surface treatments and were cleared under K040807. No new angulations were introduced. The subject worst case abutments were tested for fatigue limits and met the pre-determined success criteria. The differences between subject and predicate devices did not alter the intended use and new issues of safety and effectiveness were not raised.

Table 5 – Comparison of subject and predicate abutment Characteristics

Trade Name	MIS internal hex abutments	MIS originally cleared Internal hex abutments
510(k) Number	Subject	K040807
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 used for supporting tooth replacements to restore chewing function. The abutments in combination with two-stage endosseous implants are intended to be used as a foundation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement-retained supra-constructions.	Dental implant abutments are intended to be used in the upper or lower jaw used for supporting tooth replacements to restore chewing function. The abutments in combination with two-stage endosseous implants are intended to be used as a foundation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement-retained supra-constructions.
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) implantscan be used in a tilted manner. MIS short implants are to be used only with	The MIS dental implant system is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

	straight abutments. M4 short implants are indicated for delayed loading only..	
Materials	Healing caps, cover screws, Prosthetic Screws, Ball Attachment/Equators, cement retained abutments, temporary Ti-abutments: TI 6Al-4V ELI per ASTM F136. Gold plastic abutments: Gold Alloy Plastic cylinder: Polyoxymethylene (POM) Temporary plastic abutments: PEEK	Healing caps, cover screws, Prosthetic Screws, Ball Attachment/Equators, cement retained abutments, temporary Ti-abutments: TI 6Al-4V ELI per ASTM F136. Gold plastic abutments: Gold Alloy Plastic cylinder: Polyoxymethylene (POM) Temporary plastic abutments: PEEK
Surface treatment	Titanium: Polished and Anodized after machining	Titanium: Polished and Anodized after machining
Connection type	Internal hex	Internal hex
Angulation	NP: 0°, 10°, 20° SP: 0°, 15°, 25° WP: 0°, 15° Multi-units: 0°, 17°, 30°	NP: 0°, 10°, 20° SP: 0°, 15°, 25° WP: 0°, 15° Multi-units: 0°, 17°, 30° (K163349)

7. Non-Clinical Performance Data

As part of demonstrating the substantial equivalence of the MIS internal hex Connection Dental Implant System 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. Components that contain a TiN or anodized coating have the same materials and manufacturing methods as those in reference device K163349. The subject device is sterilized and 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.
- Fatigue Testing – Mechanical testing of MIS M4 and SEVEN internal hex implants and abutments in accordance to *ISO 14801:2016* was conducted. The worst case implants and abutments chosen for the tests were the narrowest implants loaded with the abutments which have the greatest angulation 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 they SP is a worst case in terms of diameter and wall thickness, and both SP and WP implants are made of the same material.
- Sterilization Testing –
  - For products supplied sterilized by gamma irradiation (implants, cover screws, healing caps, final drills, plastic cylinders, multi-units): Sterilization validation tests were conducted on each group of products in compliance with both ANSI/AAMI/ISO 11137-1 and ANSI/AAMI/ISO 11137-2. Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

  - For products supplied non-sterile and intended to be steam sterilized by the user (CPK kits and CPK abutments, cement retained abutments, gold abutments, temporary abutments, ball attachments and OT-equators): 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.
- For products supplied sterile, a LAL test is conducted periodically to verify the endotoxin limit is within acceptance criteria according to USP 85, USP 161 and ANSI/AAMI/ ST72.
- Disinfection Validation: for Abutments supplied non-sterile and intended to be steam sterilized by the user, 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 106 of the microbiological challenge.
- Shelf Life Testing – for the products which are supplied sterile, shelf life studies were completed by an independent testing laboratory in order to validate the integrity of the final package. The studies were conducted in accordance with ISO 11607-1. Test results were successful and supported a 5 year shelf life of the sterilized products.
- Risk Analysis - Risk analysis for MIS implants was conducted in accordance with *ISO 14971, Medical Devices: Application of Risk Analysis, for medical devices*. It was determined by MIS that all risks associated with MIS implants were acceptable and as low as reasonably possible.

8. 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.

9. 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.

10. Conclusions

The MIS internal hex implant system has the same intended use, incorporate the same fundamental technology, and has similar indications for use as the predicate. Test data to verify the performance of the MIS internal hex implant system has been provided including: dynamic fatigue, sterilization validation, shelf life, and the results of this testing, combined with the design and intended use comparison with the predicate device, support substantial equivalence.