March 16, 2018

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

Re: K173326
Trade/Device Name: MIS CONNECT Conical Connection Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 12, 2018
Received: February 12, 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*

K173326

Device Name
MIS CONNECT Conical Connection Abutment

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) 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.

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)

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510(k) SUMMARY
K173326

1. Submitter

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Date Prepared: March 15, 2018

2. Device Identification

Trade/Proprietary Name:	MIS CONNECT Conical Connection abutment
Common/Usual Name:	Dental Implant Abutment
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630;
Product Code:	NHA
Device Class:	Class II
Classification Panel:	Dental Devices Panel

3. Predicate Device(s)

Primary predicate device: MIS V3 Conical Connection Dental Implant System¬ (K163349).
Reference devices: Conical Connection Implants (K112162)

4. Device Description

The MIS CONNECT Conical Connection abutment is an endosseous dental implant abutment device which is intended for use by a dental clinician with a root-form endosseous dental implant to aid in prosthetic rehabilitation, by incorporation in the upper or lower jaw for supporting tooth replacements to restore chewing function. The MIS CONNECT Conical Connection abutment is intended to be used with MIS Conical Connection Implants, such as MIS V3 Conical Connection Dental Implant System and Conical Connection Implants cleared under K112162 and K163349, respectively, and is intended to be placed above the bone level and within the gingival tissue. The MIS CONNECT Conical Connection abutment can be fitted with a variety of complementary accessories, including Healing caps, Cementing caps and Temporary abutments (which are proposed for clearance in the present submission), and also including Prosthetic screws, Impression copings, Analogs, and Scan posts (which are class I products and are therefore exempt from clearance requirements). The MIS CONNECT Conical Connection abutment is not intended to be removed.

Components:

The MIS CONNECT Conical Connection abutment is to be used in combination with a variety of compatible superstructures (healing caps, cementing caps, and temporary abutments). The superstructures, described below, are manufactured with an external connection, ensuring compatibility to the internal connection of the MIS CONNECT Conical Connection abutment.

- *Healing caps* are premanufactured prosthetic components directly connected to the MIS CONNECT Conical Connection abutments and are indicated as temporary components to allow healing of the soft tissue. They are made from Ti-6Al-4V ELI, and supplied sterile to the user, for single use.
- *Cementing Caps* are premanufactured dental implant abutments directly connected to the MIS CONNECT Conical Connection abutments by a prosthetic screw. Cementing caps are available in anti-rotation and free-rotation and are made from Ti6Al-4V ELI, supplied non sterile, and intended for single use.
- *Temporary abutment*s are premanufactured dental implant abutments directly connected to the MIS CONNECT Conical Connection abutments, intended for use as an aid in temporary prosthetic rehabilitation, for a maximum of 180 days. They are made from Ti-6Al-4V ELI, and are available in anti-rotation and free-rotation configurations. The abutments are supplied non-sterile and intended for single use.

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) 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.

6. Substantial Equivalence Discussion

Abutments:
The predicate device for the proposed *MIS CONNECT Conical Connection abutment* is *MIS Conical Connection Multi-unit abutment* (cleared under K163349). Both devices have similar intended use and the same indications. (Note that Indications for Use of the primary predicate and reference devices are referring to implant bodies and abutments, while the subject submission only includes abutments. However, as the subject abutments are to be used with implant bodies, it is important to include the implant body indications in the subject device Indications for Use.) They are made of the same material, Ti 6Al-4V ELI, go through a similar manufacturing process, get the same color anodizing surface treatment, and are provided sterilized by gamma irradiation. Both the proposed and the predicate devices are connected directly to the implant using a conical connection without indexes, and by means of an integral external thread. In addition, both the proposed and the predicate devices are intended to be connected with a superstructure for mechanically supporting a restoration.
Differences between the connection of the proposed and predicate device to the superstructure do not raise different types of safety or effectiveness questions and are addressed by fatigue testing per ISO 14801:2007. As the proposed device's intended use is for single unit restorations, as opposed to multiple restorations for the predicate device. Testing was conducted on the reference device *MIS Conical Connection CPK abutment* (cleared under Conical Connection Implants K116162), which is also intended for single unit restorations and subjected to similar loads. The results of the testing demonstrated equivalence.

Trade Name	MIS CONNECT Conical Connection abutment Proposed device	MIS V3 Conical Connection Dental Implant System (K163349) Predicate device	Conical Connection Implants(K112162) Reference device
510(k) Number	Subject	K163349	K112162
Manufacturer	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.
Device Class	Class II	Class II	Class II
Product Code(s)	NHA	NHA, DZE	NHA, DZE
Regulation Description	Endosseous dental implant abutment	Endosseous dental implant abutment	Endosseous dental implant abutment
Regulation Number	872.3630	872.3630	872.3630
Intended use:	Dental implant abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function. The MIS CONNECT abutments in combination with endosseous implants are indicated for single or multiple unit reconstructions when screw retained prosthetics are preferred.	Dental implant abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function. The Multi-Unit abutments in combination with endosseous implants are indicated for multiple unit reconstructions when screw retained prosthetics are preferred.	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) 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.	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) 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.	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) 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.
Material(s)	Titanium 6Al-4V ELI per ASTM F136	Titanium 6Al-4V ELI per ASTM F136	Titanium 6Al-4V ELI per ASTM F136
Surface Treatment	Anodized after machined	Polished and anodized after machined	Polished and anodized after machined
Type of Connection to the Implant	Conical connection without indexes	Conical connection without indexes	Conical Connection with indexes
Type of Connection to the Superstructure	Internal connection Anti-rotation: 3 indexes Free-rotation: no indexes	External free-rotation	N/A – the reference device is an abutment being directly connected to the implant.
Gingival Height	NP: 2, 3 mm SP: 1.5, 2, 3, 4 mm WP: 1.5, 2, 3, 4 mm	1,2,3,4,5 mm	1,2,3,4 mm
Diameter	NP/SP/WP: 4 mm	NP/SP: 4.8 mm	NP: 4mm SP:4.8 and 5.5 mm WP: 5.5 mm

Trade Name	MIS CONNECT Conical Connection abutment Proposed device	MIS V3 Conical Connection Dental Implant System (K163349) Predicate device	Conical Connection Implants(K112162) Reference device
Sterilization Method	Gamma radiation	Gamma radiation	Non-sterile

Superstructures:

Healing caps, Cementing Caps, and Temporary abutments were compared to equivalent MIS V3 Conical Connection Dental Implant System superstructures cleared under K163349 which share the same indications, are made of the same materials, are manufactured in the same facility with the same manufacturing conditions and undergo equivalent surface treatments. (Note that Indications for Use of the primary predicate and reference devices are referring to implant bodies and abutments, while the subject submission only includes abutments. However, as the subject abutments are to be used with implant bodies, it is important to include the implant body indications in the subject device Indications for Use.)

No new angulations were introduced. Both the Cementing Caps and the Temporary abutments are provided straight and may not be further manufactured to have an angle; however, any of them may be used with a CONNECT abutment on two implants which diverge up to 40°, but no more than 20° per implant. Single unit loading may include angulation up to 20°. Although the predicate cement retained and temporary abutments are indicated for a divergence of 30°, the difference in divergence is accounted for in the fatigue testing.

The differences between subject and predicate devices did not alter the intended use and new issues of safety and effectiveness were not raised.

Trade Name	MIS CONNECT Superstructures Proposed device	MIS V3 Conical Connection Dental Implant System (K163349) Predicate device
510(k) Number	Subject	K163349
Manufacturer	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.
Device Class	Class II	Class II
Product Code(s)	NHA	NHA, DZE
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) 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	MIS Conical Connection Dental Implant System is 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) 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

Trade Name	MIS CONNECT Superstructures Proposed device	MIS V3 Conical Connection Dental Implant System (K163349) Predicate device
	and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	more narrow implants adjacent to one another.
Material(s)	Titanium 6Al-4V ELI per ASTM F136	Titanium 6Al-4V ELI per ASTM F136
Connection Interface	Connects to MIS CONNECT abutment mounted on an MIS Conical Connection Dental Implant	Connects directly to an MIS Conical Connection Dental Implant

7. Non-Clinical Performance Data

As part of demonstrating the substantial equivalence of the MIS CONNECT Conical Connection abutment and its compatible superstructures to the predicate and reference devices, MIS Implants Technologies completed a number of non-clinical performance tests:

- Fatigue Testing – Mechanical testing of MIS CONNECT Conical Connection abutment in accordance to ISO 14801:2007 was conducted. The test articles were able to withstand 5,000,000 cycles without failure at a substantially equivalent load to the cited reference device.
- Screw loosening testing - Mechanical testing of MIS CONNECT Conical Connection abutment under eccentric loading in a screw loosening direction, in accordance to Tsuge et al (2009). The test articles were able to demonstrate a higher release torque post loading than its initial tightening torque before loading, indicating there is no screw-loosening hazard for the proposed device during lateral dynamic loading.
- 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, 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.
- Sterilization Testing –
    - For products supplied sterilized by gamma irradiation (CONNECT abutments, healing caps): Sterilization validation tests were conducted on each group of products in compliance with 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 (cementing caps, temporary abutments): 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: 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 10^6 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.

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 and the reference 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 substantially equivalent to the reference device.

10. Conclusions

The MIS CONNECT Conical Connection abutment and superstructures have the same intended use, incorporate the same fundamental technology, and have similar indications for use as the primary predicate device.

The subject devices are therefore substantially equivalent to the primary predicate device and any differences were addressed through performance testing.