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

December 27, 2017

Re: K172505
Trade/Device Name: MIS C1 Narrow Platform Conical Connection Implant System
MIS C1 Wide Platform Conical Connection Abutments
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 30, 2017
Received: November 30, 2017

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,

Mary S. Runner -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)*
K172505

Device Name
MIS C1 Narrow Platform Conical Connection Implant System
MIS C1 Wide Platform Conical Connection Abutments

Indications for Use *(Describe)*
MIS 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 & 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, 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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K172505

510(k) Summary

1. Submitter

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Date Prepared: December 28, 2017

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3. Device Identification

Trade/Proprietary Name:	MIS C1 Narrow Platform Conical Connection Implant System MIS C1 Wide Platform Conical Connection Abutments
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: ANKYLOS C/X Implant System cleared under 510(k) K140347. Reference devices:

- A.B. DENTAL DEVICES® Dental Implants System K162482
- MIS V3 Conical Connection Dental Implant System K163349
- MIS Conical Connection Implants K112162
- Straumann NNC Protective Caps K113410

5. Device Description

The MIS C1 NP Conical Connection dental implants are manufactured from Ti-6Al-4V ELI. The conical root-shaped, screw-type implants are designed for both two-stage and single stage procedures, with one internal thread for screwed abutment. The implants are self-tapping, root-form with tapered threads. They have a 3.3 mm diameter and the following lengths: 10mm, 11.5mm, 13mm and 16mm. The internal part of the implant and the lower part of the abutment are anodized for coloring purposes for a quick identification of the diameter and to ensure the use of the adequate abutments. The Implants are supplied sterile.

This submission also includes wide platform (WP) conical connection abutments which are compatible to the previously cleared (K112162) MIS conical connection wide platform implants.

Components:

The MIS C1 Conical Connection Dental Implant is to be used in combination with a variety of conical connection 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). These abutments are manufactured with a conical connection, ensuring compatibility to the conical connection implants. The abutments in this submission include NP abutments, compatible with the C1 NP implants also submitted here; and WP abutments compatible with previously cleared (K112162) MIS conical connection WP implants.

- *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. Cement retained abutments are available straight or angulated, in different heights and diameters. The angulated abutments allow a maximum angulation of 25º. The straight abutments are intended for 0 degree angulation and straight implantation only. They are made of Ti6Al-4V ELI, and supplied non sterile, to be steam sterilized by the user according to the labeling, intended for single use.
- *CPK abutments* are cement retained abutments intended to be used in temporary and permanent prosthetic rehabilitation. CPK abutments are intended for 0º angulation and straight implantation only. They are supplied non sterile, to be steam sterilized by the user according to the labeling, and intended for single use.
- *Plastic healing caps* are premanufactured abutments intended to cover the CPK abutment until the permanent restoration is ready. They are made from PEEK and intended to be used for up to 180 days. The plastic healing caps are delivered non sterile to the user, for single use, to be sterilized by steam sterilization. Different caps are available for use with narrow, standard, and wide platforms.
- *Gold Plastic abutments* are 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 alloy, and the upper part is made of plastic. The plastic part is dissolved once the casting is done. Gold abutments are intended for 0º angulation and 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 abutments* are indicated for multiple unit reconstructions when screw retained prosthetics is preferred. Multi-unit abutments allow either direct screw of the prosthesis into the multi-unit abutment or connection to a fixed overdenture bar. Multi-units are available in angulations between 17-30º. The Multi units are made of Ti-6Al-4V ELI. They are supplied sterile and intended for single use.
- *OT-Equators & Ball Attachments* are screw retained dental implant abutments connected directly to the endosseous dental implant by their lower threaded part, and are used in completely edentulous jaws for anchoring an overdenture to allow its insertion and removal.
- *Temporary abutments* are premanufactured dental implant abutments directly connected to the endosseous dental implant, intended for use as an aid in temporary prosthetic rehabilitation, for a maximum of 180 days. They are available in Ti-6Al-4V ELI and in natural PEEK, and in anti-rotation and free-rotation. The abutments are supplied non sterile, to be steam sterilized by the user according to the labeling and intended for single use.

6. Indications for Use

MIS 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 & 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, 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.

7. Substantial Equivalence Discussion

a. Implants: The predicate device for the MIS C1 NP conical connection dental implants is the ANKYLOS C/X (K140347). Both devices have similar indications, although the predicate device states that implants 6.6 mm in length are for two-stage surgical procedures and cemented, removable or screw retained restorations. The subject device does not contain this limitation as its shortest device is 10 mm in length. The length range of the subject device is within the range of the predicate. Although the diameter of the subject device is somewhat smaller, 3.3 vs 3.5 mm, it possesses at least equivalent strength as compared to the predicate device. Their geometrical design is similar with minor differences which do not raise different safety or efficacy questions. Fatigue testing per ISO 14801:2007 assessed the impact of these differences and demonstrates at least equivalent performance. The predicate device is indicated for all positions in the jaws, while the subject C1 NP implants are indicated for the mandibular central, lateral incisor and maxillary lateral incisor regions, and must be splinted if using two or more narrow implants adjacent to one another. 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. A reference device, A.B. DENTAL DEVICES® Dental Implants System (K162482) with the same 3.3mm diameter and similar indications for use as the subject device is also

presented. A comparison of implant characteristics demonstrates substantial equivalence to the predicate device.

Table 1: Comparison of subject and predicate Implants

Trade Name	MIS C1 NP Conical Connection Dental Implants	ANKYLOS C/X Implant System	A.B. DENTAL DEVICES® Dental Implants System
510(k) Number	K172505	K140347	K162482
Manufacturer	MIS Implants Technologies Ltd.	DENTSPLY Implants	A.B. Dental Device 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 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 & 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, 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.	ANKYLOS® C/X Implants of 8 mm in length or longer are for single-stage or two-stage surgical procedures and cemented, removable or screw retained restorations. The ANKYLOS® C/X Implants may be used for immediate placement and function on single tooth and/or multiple tooth applications when adequate primary stability is achievable, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted. ANKYLOS® C/X Implants of 6.6 mm in length are for two-stage surgical procedures and cemented, removable or screw retained restorations. The ANKYLOS® C/X Implants may be used for immediate placement on single tooth and/or multiple tooth applications when adequate primary stability is achievable, with appropriate occlusal loading, in order to restore chewing function.	A.B. DENTAL DEVICES® Dental Implants 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. A.B. DENTAL DEVICES® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: I22, I5, I55, I10. P4 and P14 angled abutments are to be used only with standard platform implants 3.5 mm in diameter or larger.

		Multiple tooth applications may be splinted.	
Implant Material	Titanium 6Al-4V ELI per ASTM F136	CP Titanium grade 2	Titanium 6Al-4V ELI
Surface Treatment	Anodized ,sand blasted and acid etched	Sand blasted and acid etched	Sand blasted with CaP, except for 0.5mm distal part of the neck which is smooth.
Body design	Tapered design, threaded	Tapered design, threaded	Tapered design, threaded
Connection Type	Conical with indexes	Conical with indexes	Conical with internal hex
Type of implant	Bone level implant	Bone level implant	Bone level implant
Implant Diameters	3.3 mm	3.5 mm	Ø 3.3 mm
Implant Lengths	10, 11.5, 13 and 16 mm	6.6, 8, 9.5, 11, 14, 17 mm	10, 11.5, 13 and 16 mm
Neck Design	Cylindrical	Cylindrical	Cylindrical
Apex	Domed apex	Domed apex	Flat apex
Thread	Dual	Dual	Dual
Sterilization Method	Radiation	Radiation	Radiation

b. 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 conical 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 K163349. No new angulations were introduced. The subject worst case abutment was 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 2 – Comparison of subject and predicate Abutments Characteristics

Trade Name	**MIS C1 Conical Connection Abutments**	**MIS V3 Conical Connection Abutments**
510(k) Number	Subject	K166349
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	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

Trade Name	MIS C1 Conical Connection Abutments	MIS V3 Conical Connection Abutments
	foundation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement-retained supra-constructions.	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 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 & 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, 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 V3 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 more narrow implants adjacent to one another.
Material(s)	Healing caps, cover screws, Prosthetic Screws, Ball Attachment/Equators, cement retained abutments: TI 6Al-4V ELI per ASTM F136 Gold plastic abutments: Gold Alloy Plastic cylinder: Polyoxymethylene (POM) Temporary plastic abutments and plastic healing caps: PEEK	Healing caps, cover screws, Prosthetic Screws, Ball Attachment/Equators, cement retained 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
Angulation	NP: 0°, 10°, 20° WP: 0°, 15°, 17°, 25°, 30°	NP 0°, 10°, 20° SP: 0°, 15°, 17°, 25°, 30°

8. Non-Clinical Performance Data

As part of demonstrating the substantial equivalence of the C1 NP Conical Connection Dental Implant system and the MIS WP conical connection abutments to the predicate devices, 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, 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 C1 implants and abutments in accordance to ISO 14801:2007 was conducted. The worst case narrow platform implant and abutment chosen for the

test was the narrowest implant loaded with the abutment which has the greatest angulation. The test articles were able to withstand 5,000,000 cycles without failure at a substantially equivalent load to the cited predicates. Wide platform abutments were not tested for fatigue because they did not pose a new worst case compared to the cleared standard platform abutments in terms of raw material, diameter, wall thickness and moment arm.

- 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.

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

The MIS C1 NP conical connection implant system and WP abutments 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 C1 NP conical connection implant system and WP abutments 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.