DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 26, 2017

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

Re: K163349
Trade/Device Name: MIS V3 Conical Connection Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 18, 2017
Received: May 18, 2017

Dear Arbel Shezaf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -S6

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163349

Device Name

MIS V3 Conical Connection Dental Implant System

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K163349

510(k) Summary

1. Submitter

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Date Prepared: May 23, 2017

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3. Device Identification

Trade/Proprietary Name:	MIS V3 Conical Connection 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:

- ASTRA TECH OsseoSpeed TX S from Astra Tech AB cleared under 510(k) K101732

Reference devices:

- MIS Conical Connection Implants from MIS Implants Technologies cleared under 510(k) K112162.
- ANKYLOS C/X Dental Implant System from Dentsply International cleared under 510(k) K140347.
- NobelActive Internal Connection Implants from Nobel BioCare cleared under 510(k) K071370.
- UTA and UHA cleared under 510(k) K102467.

- Multi-Unit Abutments for AstraTech, Camlog and Ankylos Implant Systems from Nobel BioCare cleared under 510(k) K061477.

5. Device Description

The MIS V3 Conical Connection implants are manufactured from titanium (Ti-6Al-4V ELI complying with standard *ASTM F136-13 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant*). The cylinder screw type implants are designed for both two-stage and single stage procedures, with one internal thread for screwed abutment. They have an internal conical connection with an anti-rotation index of six directions for Standard Platform Implants and three directions for Narrow Platform Implants.

The implants are self-tapping, root-form with tapered threads. They feature a tri-surface crestal contact, built-in platform switching and a flat apex enabling grip into bone.

The MIS V3 Conical Connection Implants are provided in 3.3, 3.9, 4.3 and 5.0 mm diameters and with the following lengths:

- 3.3 mm diameter: 10mm, 11.5mm, 13mm and 16mm
- 3. 9mm diameter: 8mm, 10mm, 11.5mm, 13mm and 16mm
- 4.3mm diameter: 8mm, 10mm, 11.5mm, 13mm and 16mm
- 5.0mm diameter: 8mm, 10mm, 11.5mm, 13mm and 16mm

The implants surface is sand blasted and acid etched.

The MIS V3 Conical Connection Dental Implant System is to be used in combination with a wide range of abutments provided in order to aid in the prosthetic rehabilitation.

For a quick identification of the diameters and to ensure the use of the adequate 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), the internal part of the implant is anodized for coloring purposes as follows:

- “Narrow Platform” (NP) – 3.3mm diameter: blue
- “Standard Platform”(SP) - 3.9mm, 4.3mm and 5.0 diameters: purple

The MIS V3 Conical Connection Implant package comes with a sterile, single-use final drill (packaged in a sterile pouch).

Components:

The MIS V3 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.

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. Later on, the crown is cemented to the abutment. Cement retained abutments are available straight or angulated, in different heights and diameters to accommodate specific needs according to the patient. The angulated abutments allow a maximum angulation of 25º. The straight abutments are intended for 0° 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 premanufactured abutments directly connected to the endosseous dental implant by a prosthetic screw, which is supplied with the abutments. They are intended to be used in temporary and permanent prosthetic rehabilitation. CPK abutments are intended for 0° angulation and straight implantation only. They are cement retained, meaning the crown is cemented to the abutment. 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 T-6Al-4V ELI, while their additional components are made of POM. 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 dissolved once the casting is done. 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 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 abutment*s are premanufactured dental implant abutments directly connected to the endosseous dental implant. They 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 both straight and angulated, with a maximum of 30º angulation. 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 used in completely edentulous jaws for anchoring an overdenture to allow its insertion and removal. OT-Equators and Ball attachments

allow a maximum of 15º angulation. Ball attachments have a higher profile and ball shaped head, while the OT equators have a lower profile and a truncated head. Both are made from Ti6Al-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, for a maximum of 180 days. 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. Free rotation temporary abutments allow a maximum of 15º angulation. Anti-rotation temporary abutments are intended for 0° angulation and straight implantation only. Directions and limitations for modifications are given 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.

For a quick and simple identification of the diameters and in order to ensure the use of the proper abutment with the right implant, the components are colored by anodizing as follows:

- "Narrow Platform"(NP) – 3.3mm diameter, blue
- "Standard Platform"(SP) - 3.9mm, 4.3mm and 5.0 diameters: purple

6. Indications for Use

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.

7. 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.

The main difference is in the subject device's indication for narrow platform implants, regarding the need for splinting mandibular central and lateral incisors when using two or more narrow implants

adjacent to one another. We believe this indication only improves the safety of the narrow implants as compared to the predicate device and does not alter the intended use.

The subject and predicate devices have the same intended use and similar indications for use. Their geometrical design is similar with minor differences which do not raise different safety or efficacy questions. The following tables compare the MIS V3 Conical Connection Dental Implant System to the predicate devices with respect to indications for use, principles of operation, technological characteristics and materials.

Under each table is a discussion of the differences and similarities.

Table 1 – Comparison of Endosseous Implant Characteristics – Narrow Platform

Trade Name	MIS V3 Conical Connection Dental Implant System, Narrow Platform	ASTRA TECH OsseoSpeed TX S
510(k) Number	Subject	K101732
Manufacturer	MIS Implants Technologies Ltd.	Astra Tech AB
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 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	The OsseoSpeed implants are intended to be used: • to replace missing teeth in single or multiple unit applications within the mandible or maxilla • for immediate placement in extraction sites and partially or completely healed alveolar ridge situations •for both one- and two-stage surgical procedures • especially well in soft bone applications where implants with other implant surface treatments may be less effective • together with immediate loading

	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.	protocol in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate • together with immediate loading protocol for single-tooth restorations on implants 8 mm or longer • with its 3.0 S product line for maxillary lateral incisors and mandibular lateral and central incisors.
Endosseous Implant Material(s)	Titanium 6Al-4V ELI per ASTM F136	Titanium grade 4
Surface Treatment	Anodized ,sand blasted and acid etched	TiO2-blasted fluoride-modified surface.
Body design	Tapered design, threaded	Cylindrical, threaded
Connection Type	Conical, 3 indexes, cone angulation 12°	Internal, double hex conical connection, cone angulation 21°
Type of implant	Bone level implant	Bone level implant
Implant Diameters	Ø 3.3 mm	Ø 3.5 mm
Implant Lengths	10, 11.5, 13 and 16 mm	8, 9, 11, 13, 15 and 17 mm
Neck Design	Three-way cutaway longitude implant axis at the cervical part of the implant	Cylindrical
Apex	Flat apex	Flat apex
Thread	Dual	Dual
Sterilization Method	Radiation	Radiation

The length range of the subject 3.3 mm MIS V3 is 10 -16 mm. which is within the range of the predicate (8 – 17 mm).

Although the diameter of the subject device is 3.3 mm, it possesses at least equivalent strength as tested and compared to the predicate device of larger diameter (3.5 mm), likely due to the use of Ti alloy (ASTM F136) which has a higher tensile strength compared to the predicate which uses C.P. Ti grade 4. Despite the difference in the connection type, both connections provide a locking mechanism for a tight fit. Similarly, although there are minor differences in threading, body design (tapered vs. cylindrical), neck design and surface treatment, these differences 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.

Table 2 – Comparison of Endosseous Implant Characteristics – Standard Platform Ø3.9 and 4.3 mm

Trade Name	MIS V3 Conical Connection Dental Implant System Standard Platform Ø3.9 and 4.3 mm	MIS Conical Connection Implants Ø3.75 and 4.20mm	ASTRA TECH OsseoSpeed TX S
510(k) Number	Subject	K112162	K101732
Manufacturer	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.	Astra Tech AB
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 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	MIS Conical Connection 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 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 OsseoSpeed implants are intended to be used: • to replace missing teeth in single or multiple unit applications within the mandible or maxilla • for immediate placement in extraction sites and partially or completely healed alveolar ridge situations •for both one- and two-stage surgical procedures • especially well in soft bone applications where implants with other implant surface treatments may be less effective • together with immediate loading protocol in all indications, except in single tooth situations in soft

Trade Name	MIS V3 Conical Connection Dental Implant System Standard Platform Ø3.9 and 4.3 mm	MIS Conical Connection Implants Ø3.75 and 4.20mm	ASTRA TECH OsseoSpeed TX S
	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.		bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate • together with immediate loading protocol for single-tooth restorations on implants 8 mm or longer • with its 3.0 S product line for maxillary lateral incisors and mandibular lateral and central incisors.
Endosseous 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	Anodized ,sand blasted and acid etched	TiO2-blasted fluoride-modified surface.
Body design	Tapered design, threaded	Tapered design, threaded	Cylindrical, threaded
Connection Type	Conical – 6 indexes, cone angulation 12°	Conical – 6 indexes, cone angulation 12°	Internal, double hex conical connection, cone angulation 21°
Type of implant	Bone level implant	Bone level implant	Bone level implant
Implant Diameters	Ø 3.90 and 4.30 mm	Ø 3.75 and 4.2 mm	Ø 3.5, 4.0 mm
Implant Lengths	8, 10, 11.5, 13 and 16 mm	8, 10, 11.5, 13 and 16 mm	3.5 mm: 8, 9, 11, 13, 15 and 17 mm 4.0 mm: 6-17 mm
Neck Design	Three-way cutaway longitude implant axis at the cervical part of the implant	Cylindrical	Cylindrical
Apex	Flat apex	Domed apex	Flat apex
Thread	Dual	Dual	Dual
Sterilization Method	Radiation	Radiation	Radiation

The subject and predicate devices have similar indications. The length range of the subject 3.9 and 4.3 mm MIS V3 is 8 -16 mm which is the same range of the predicate C1, and within the range of the predicate ASTRA TECH OsseoSpeed (6 – 17 mm). Both subject device and predicate C1 have a tapered

body design, a similar conical connection with the same number of indexes, and undergo the same surface treatment. The ASTRA TECH predicate has a cylindrical body design, and an internal, double hex conical connection. The subject device and C1 predicate are both made from Ti-6Al-4V ELI while the ASTRA TECH OsseoSpeed TX S is made from CP Titanium grade 4. Although there are minor differences in diameter, threading, apex and neck design, these differences are common endosseous implants and 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, as demonstrated in the performance testing for the subject V3 Conical Connection Implants and for the predicates C1 and ASTRA TECH OsseoSpeed TX S.

Table 3 – Comparison of Endosseous Implant Characteristics – Standard Platform Ø5.0 mm

Trade Name	MIS V3 Conical Connection Dental Implant System, Standard Platform Ø5.0 mm	ANKYLOS C/X Implant System Ø5.5 mm
510(k) Number	Subject	K140347
Manufacturer	MIS Implants Technologies Ltd.	Dentsply International, Inc.
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 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	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®

Trade Name	MIS V3 Conical Connection Dental Implant System, Standard Platform Ø5.0 mm	ANKYLOS C/X Implant System Ø5.5 mm
	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.	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. Multiple tooth applications may be splinted.
Endosseous Implant Material(s)	Titanium 6Al-4V ELI per ASTM F136	CP Titanium grade 2
Surface Treatment	Anodized , sand blasted and acid etched	Sand blasted and acid etched
Body design	Tapered design, threaded	Tapered design, threaded
Connection Type	Conical – 6 indexes Cone angulation 12°	Conical: 6 indexes Cone angulation 11°
Type of implant	Bone level implant	Bone level implant
Implant Diameters	Ø 5.0 mm	Ø5.5 mm
Implant Lengths	8, 10, 11.5, 13 and 16 mm	6.6, 8, 9.5, 11, 14 and 17 mm
Neck Design	Three-way cutaway longitude implant axis at the cervical part of the implant	Cylindrical
Apex	Flat apex	Domed apex
Thread	Dual	Dual
Sterilization Method	Radiation	Radiation

Both subject and predicate devices have similar indications, and while there are differences in wording, both are indicated for one or two stage surgical procedures, for either cement or screw retained restorations, with the purpose of restoring chewing function. The length range of the subject 5.0 mm MIS V3 is 8 -16 mm. which is within the range of the predicate ANKYLOS (6.6 – 17 mm). They share a tapered body design, similar conical connection with the same number of indexes, and undergo similar surface treatment with the exception of anodization treatment to internal part of the subject device's implant. Although the subject device's diameter of 5.0 mm is smaller than the predicate (5.5 mm), and there are minor differences in threading, apex and neck design, fatigue testing per ISO 14801:2007 assessed the impact of these differences and demonstrates at least equivalent performance. The difference in the materials between the subject and predicate devices, does not affect the safety and effectiveness of the subject device since Titanium-6Al-4V ELI alloy, has a higher tensile strength compared to the predicate's material, CP-Titanium grade 2.

Table 4 – Comparison of Endosseous Abutments Characteristics

Trade Name	MIS V3 Conical Connection Abutments	C1 Conical Connection Abutments	Nobel BioCare
510(k) Number	Subject	K112162	K071370
Manufacturer	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.	NobelActive Internal Connection Implants
Device Class	Class II	Class II	Class II
Product Code(s)	NHA	NHA	NHA
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 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.	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 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	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.	NobelActive Internal Connection Implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing

Trade Name	MIS V3 Conical Connection Abutments	C1 Conical Connection Abutments	Nobel BioCare
	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	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.	function to partially or fully edentulous patients. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied. The NobelActive 3.0 implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.

Trade Name	MIS V3 Conical Connection Abutments	C1 Conical Connection Abutments	Nobel BioCare
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: 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	Abutments: TI 6Al-4V ELI per ASTM F136 Abutment screws: TI 6Al-4V Temporary Plastic Abutments: Polyetheretherketone (PEEK)
Surface Treatment	Polished and Anodized after machining	Polished and Anodized after machining	Polished and Anodized after machining
Angulation	NP 0°, 10°, 20° SP 0°, 15°, 17°, 25°, 30°	SP: 0°,15°,25°	RP : 0°,17°,30°

Healing caps, cover screws, cement retained abutments, CPK abutments, gold 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, are manufactured in the same facility with the same manufacturing conditions and undergo the same surface treatments. The differences between the subject and predicate devices are additional platforms and diameters, with no new gingival heights or angulations. The new narrow platform abutments and differences in diameter were performance tested with their compatible implant and showed at least equivalent performance to the predicates and therefore did not raise new issues of safety and effectiveness.

Temporary abutments and multi-units were compared to Nobel Biocare's temporary abutments and multi-units. The temporary abutments share similar intended use, materials and angulations, and are both intended for up to 180 days of use. The multi units share similar intended use, materials and angulations. Both temporary abutments and multi units differ from their predicates in connection type but both of the connection types provide a locking mechanism for a tight fit. The subject multi-units were fatigue tested 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.

8. Non-Clinical Performance Data

As part of demonstrating the substantial equivalence of the V3 Conical 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. The MIS V3 Conical Connection Dental Implant System was tested in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- 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, K112162. The subject device is sterilized and packaged using identical materials and processing as the predicate, K112162. Finally the subject device has the same intended use, patient contact duration and type as the predicate, K112162. For these reasons, biocompatibility testing was not required to support the substantial equivalence of the subject device.

- Fatigue Testing – Mechanical testing of MIS V3 implants and abutments 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 predicates.

- Sterilization Testing – Sterilization validation tests were conducted in compliance with ANSI/AAMI/ISO 11137-1:06 and EN ISO 11137-2:12 for the MIS V3 Conical Connection Dental Implant System. Test results have demonstrated that the SAL of 10-6 was achieved and all testing requirements were met. Steam sterilization parameters were validated for 2 methods: gravity displacement and pre-vacuum steam sterilization. The studies were conducted in accordance with ISO 17665-1:2006 and demonstrated a SAL of 10^{-6}.

- Shelf Life Testing – Shelf life testing of real-time aged implants to validate the integrity of the final package was completed by an independent testing laboratory. Test results were successful and consisted of a sterility testing of product which had been aged real-time for at least five years. No growth was determined for the samples provided for this testing. Additional burst testing had been completed by contract packager.

- 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

Based on the comparison of the indications for use, the technological characteristics and the performance testing it was concluded that the MIS V3 Dental Implant System it substantially equivalent to the predicate devices.