DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 19, 2017

IlerImplant S.L.
c/o Alexandre Pétiard
Senior Consultant, Regulatory
Emergo Global Consulting, LLC
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K161593
Trade/Device Name: GMI Frontier Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: December 22, 2016
Received: December 27, 2016

Dear Alexandre Pétiard:

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 yours,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161593

Device Name
GMI Frontier Dental Implant System

Indications for Use *(Describe)*
GMI Frontier Dental Implant System model is intended to be used for surgical placement in upper or lower jaw to provide a support for prosthetic devices such as artificial teeth, in order to restore the patient's chewing function. The GMI Frontier Dental Implants System is intended for delayed loading.

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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510(k) Summary

GMI Frontier Dental Implant System

K161593

1. Submission Sponsor

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3. Date Prepared

January 17th, 2017

4. Device Identification

Trade/Proprietary Name:	GMI Frontier Dental Implant System
Common/Usual Name:	Endosseous dental implant
Classification Name:	Endosseous dental implant
Regulation Number:	872.3640
Product Code:	DZE
Subsequent Product Code:	NHA
Device Class:	Class II
Classification Panel:	Dental

5. Legally Marketed Predicate Device(s)

Primary predicate

K040807 MIS Dental Implant System (MIS – Implant Technologies Ltd)

Reference predicates

K142211 OT Equator (Rhein '83 SRL)

K142260 NobelActive (Nobel Biocare AB)

6. Device Description

GMI Frontier consists of dental implant, attachments (straight and angled abutments, healing abutments, ball abutments, temporary cylinders, straight and angled multi-esthetic abutments and their accessories), and clinical screws.

6.1 Implant

Dental implants (DZE - 872.3640 – Class II) are used on patients who have lost a single tooth or who are partially or completely edentulous and their main function is to restore mastication. Dental implants are made of titanium (ISO 5832-2 and ASTM F-67 compliant) with a length from 8 to 17mm, a diameter from 3.30 to 5.75mm, a RP or WP platform and a hexagonal connection. Dental implants are tapered, self-threading, root-form endosteal implants that have been designed to be placed fully submerged in two surgical stages: a first osteointegration stage and a loading stage.

6.2 Abutments

Dental abutments (NHA - 872.3630 – Class II) or also referred to as attachments are used on patients who have lost a single tooth or who are partially or completely edentulous and their main function is to restore mastication. Dental Attachments are all made of titanium (ISO 5832-3 and ASTM F-136

compliant) with the exception of temporary cylinder that are made of Polyetheretherketone or PEEK (ASTM F2026-12 compliant).

The Dental Implant are connected to the following abutments through a hexagonal connection:

- Angled (15 -20°) abutment with a length of 11mm using a RP or WP platform. The abutments are intended to create final cement-retained single or multi-unit restorations when an implant angle correction is needed, to allow the parallelization of the prosthesis in relation with the adjacent natural or prosthetic teeth.
- Straight abutment with a length from 10.25 to 12.25mm using a RP or WP platform and gingival height from 1.5 to 3.5mm. The abutments are intended to create final cement-retained single or multi-unit restorations when an implant angle correction is not needed.
- Straight implant carrier abutments with a length of 8.7 mm using a RP or WP platform and gingival height of 1.5mm. The abutments have three possible intended uses: they are intended to be used as implant carrier, to insert the implant in the bone bed, to create temporal or final cement-retained single or multi-unit restorations when an implant angle correction is not needed, and as basis for the closed tray impression procedure when it is used in conjunction with the plastic CT impression coping.
- Straight temporary cylinders with a length of 12mm using a RP or WP platform. The abutments are intended to create temporary cement or screw-retained restorations when an implant angle correction is not needed. The non-rotary version is used for single restorations and the rotary version is for multiple restorations.
- Straight ball abutments (Ball abutment plus retention kit) with a length from 9.9 to 12.9mm using a RP or WP platform and gingival height from 1.0 to 4.0mm. The abutments are intended to create tissue-supported overdentures.
- Straight anatomic or non-anatomic healing abutments with a length from 7.6 to 11.6mm using a RP or WP platform, gingival height from 2.0 to 6.0mm and a diameter from 4.0 to 6.0mm. The abutments are intended to create the mucosal route between the implant connection and the prosthesis throughout the soft tissues. The anatomic healing abutments have an emergence profile that allow them match with the abutment shape.
- Straight multi-esthetic abutments and their accessories with a length from 8 to 11.1mm using a RP or WP platform and a gingival height from 1.0 to 4.0mm. The abutments used in conjunction with ME temporary cylinders are intended to create temporary screw-retained full-arch restorations with an existing or new acrylic overdenture, when an implant angle correction is not needed
- Angled (17 – 30°) multi-esthetic abutments and their accessories with a length from 6.2 to 7.2mm using a RP platform and a gingival height from 2.5 to 4.0mm. The abutments used in conjunction with ME temporary cylinders are intended to create temporary screw-retained full-arch restorations with an existing or new acrylic overdenture, when an implant angle correction is needed.

The abutments are connected to the top of the implant either through a "clinic screw" or directly attached when it is composed of a threaded part.

Multi-esthetic abutments are used with their accessories composed of:

- Multi-Esthetic Healing Cap made of Titanium (ISO 5832-3 and ASTM F-136 compliant) responsible for generating a mucosal route to connect the Multi-Esthetic abutment to the secondary structure or prosthesis, once osseointegration is completed,
- Multi-Esthetic Temporary Cylinder made of Titanium (ISO 5832-3 and ASTM F-136 compliant) are intended to create temporary screw-retained full-arch restorations with an existing or new acrylic overdenture, when an implant angle correction is not needed and is fixed to the top of the Multi-Esthetic abutment using a multi-esthetic clinic screw.
- Multi-Esthetic Clinical Screw made of Titanium (ISO 5832-3 and ASTM F-136 compliant) is used in combination with Multi-Esthetic Temporary Cylinder as detailed above.

6.3 Clinic screws

A clinic screw (NHA - 872.3630 – Class II) is used for the final anchoring of abutments to the implant. The clinic screws are made of Titanium (ISO 5832-3 and ASTM F-136 compliant). They are straight with a hexagonal connection.

7. Indication for Use Statement

GMI Frontier Dental Implant System model is intended to be used for surgical placement in upper or lower jaw to provide a support for prosthetic devices such as artificial teeth, in order to restore the patient's chewing function. The GMI Frontier Dental Implants System is intended for delayed loading.

8. Substantial Equivalence Discussion

The following table compares the GMI Frontier Dental Implant System to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics with MIS Dental Implant System

Manufacturer	**IlerImplant**	**MIS – Implant Technologies, LTD.**	**Significant Differences**
Trade Name	**GMI Frontier Dental Implant System**	**MIS Dental Implant System**	
510(k) Number	K161593	K040807	*NA*
Product Code	DZE, NHA	DZE, NHA	*Same*
Regulation Number	872.3640	872.3640	*Same*
Regulation Name	Endosseous dental	Endosseous dental	*Same*

Manufacturer	**IlerImplant**	**MIS – Implant Technologies, LTD.**	**Significant Differences**
Trade Name	**GMI Frontier Dental Implant System**	**MIS Dental Implant System**	
	implant	implant	
Indications for Use	GMI Frontier Dental Implant System model is intended to be used for surgical placement in upper or lower jaw to provide a support for prosthetic devices such as artificial teeth, in order to restore the patient's chewing function. The GMI Frontier Dental Implants System is intended for delayed loading.	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.	*Substantially Equivalent, the indications for use are both for surgical placement in upper or lower jaw to provide a support for prosthetic devices to restore the patient's chewing function.*
<u>Implant</u>			
Loading	Delayed	Immediate and delayed	*Substantially Equivalent, both are used for delayed loading.*
Thread	Threaded	Threaded	*Same*
Implant Type	Root form endosseous implant	Root form endosseous implant	*Same*
Connection	Internal Hex	Internal Hex	*Same*
Body Ø (mm)	3.30, 3.75, 4.25, 4.75, 5.75	3.30, 3.75, 4.20, 5.0, 6.0	*Substantially equivalent, the range of body diameter of GMI Frontier Dental Implant System is within the range of body diameter of MIS Dental Implant System.*
Platform Ø (mm)	RP: 3.30 / WP: 4.30	NP: 3.30 / RP: 3.75 / WP: 4.50	*Substantially equivalent, fatigue and static mechanical strength of GMI Frontier Dental Implant System is higher than the anatomical loads that can be applied and is comparable to the predicate device.*

Manufacturer	**IlerImplant**	**MIS – Implant Technologies, LTD.**	**Significant Differences**
Trade Name	**GMI Frontier Dental Implant System**	**MIS Dental Implant System**	
Length (mm)	8, 10, 11.5, 13, 15, 17 Note: all implant lengths are available in all implant diameters with the following exceptions: - 15mm implant length is only for 3.30, 3.75, and 4.25mm implant diameter. - 17mm implant length is only for 3.75 and 4.25mm implant diameters	8, 10, 11.5, 13, 16 Note: all implant lengths are available in all implant diameters with the following exception: - 8mm implant length is only for 3.75, 4.20, 5.00 and 6.00mm implant diameters - 16mm implant length is only for 3.30, 3.75, 4.20, 5.00mm implant diameters	*Substantially equivalent, at the critical fracture point, all implants length including 17 mm have the same design and dimensions and can support the same strength. The critical fracture point is not affected by the additional length of implants (i.e. 17 mm) compared to the predicate device. Moreover, the reference device NobelActive (K142260) includes a 17.5mm implant length with the 3.50 and 4.30mm implant diameters.*
Shape	Screw type	Screw type	*Same*
Rotation	60°	60°	*Same*
Surface	Sand Blasted and acid etched	Sand Blasted and acid etched	*Same*
Packaging	Double packaging	Double packaging	*Same*
Sterilization	Gamma Radiation	Gamma Radiation	*Same*
Material	Titanium	Titanium	*Same*
<u>Abutments</u>			
Abutment Type	- Straight and angled abutments - Temporaty cylinder abutments - Ball Abutments - Multi esthetic abutments	- Straight and angled abutments - Ti bases abutments - Temporaty cylinder abutments - Ball Abutments - Multi esthetic abutments	*Substantially equivalent, the range of abutment types of GMI Frontier Dental Implant System is within the range of abutment types of MIS Dental Implant System.*
Angulation	Straight or Angled up to 30°: - 17° and 30° for ME	Straight Angled up to 30°	*Same*

Manufacturer	IlerImplant	MIS – Implant Technologies, LTD.	Significant Differences
Trade Name	**GMI Frontier Dental Implant System**	**MIS Dental Implant System**	
	abutment - 15° and 20° for the angled abutments		
Material	Titanium PEEK	Titanium PEEK	*Same*
Platforms	RP / WP	NP / RP / WP	*Substantially Equivalent, the abutment platforms are suitable to the implant platforms. Fatigue and/or static mechanical strength for the abutments of GMI Frontier Dental Implant System is higher than the anatomical loads that can be applied and is comparable to the predicate device.*
Model	Straight (S) Anatomic (A) Esthetic (E) Non-Esthetic (NE)	Straight (S) Anatomic (A) Esthetic (E) Non-Esthetic (NE)	*Same*
Gingival Height (mm)	1 to 6 mm	1 to 8 mm	*Substantially Equivalent, the range of height for abutments of GMI Frontier Dental Implant System is within the range of height for abutments of MIS Dental Implant System.*
Length (mm)	6.25 to 12.9 mm	6 to 13mm	*Substantially Equivalent, the range of length for abutments of GMI Frontier Dental Implant System is within the range of length for abutments of MIS Dental Implant System.*
Connection	Internal hex	Internal hex	*Same*
Sterility	Non-sterile	Non-sterile	*Same*
Clinic screws			
Angulation	Straight	Straight	*Same*

Manufacturer	**IlerImplant**	**MIS – Implant Technologies, LTD.**	**Significant Differences**
Trade Name	**GMI Frontier Dental Implant System**	**MIS Dental Implant System**	
Material	Titanium	Titanium	*Same*
Size	M1.8	U-72 UNF SAE	*Substantially Equivalent, the two threads only differ on the diameter (difference: 0.05 mm) and on the pitch (0.003 mm).*
Connection	Internal hex	Internal hex	*Same*
Sterility	Non-sterile	Non-sterile	*Same*
Multi esthetic abutments accessories			
Angulation	Straight	Straight	*Same*
Material	Titanium	Titanium	*Same*
Platform diameter (mm)	4.8 / 6.0	4.5	*Substantially Equivalent, a longer accessory do not change the functionality of GMI Frontier Dental Implant System compared to the predicate device.*
Connection	Conical (Multi-Unit Cone)	Conical	*Substantially Equivalent, a reference device cleared by the FDA includes the same conical connection with multi-unit cone as GMI Frontier Dental Implant System.*
Sterility	Non-sterile	Non-sterile	*Same*

9. Non-Clinical Performance Data

As part of demonstrating the GMI Frontier Dental Implant System substantial equivalence to the predicate devices that are subject to this 510(k) submission, IlerImplant completed a number of non-clinical performance tests. The GMI Frontier Dental Implant System meets all the requirements for overall design, sterilization, and biocompatibility results confirming that the design output meets the design inputs and specifications for the device.

The GMI Frontier Dental Implant System passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility evaluation (ISO 10993-1:2009 and ISO 7405:2008):

- Cytotoxiticy test (ISO 10993-5:2009)
- Intracutaneous Reactivity Test (ISO 10993-10:2010)
- Delayed Hypersensitivity Test (ISO 10993-10:2010)
- Acute Systemic Toxicity Test (ISO 10993-11:2006)
- Bacterial Reverse Mutation Assay Test (ISO 10993-3:2014)
- Mouse Lymphoma Test (ISO 10993-3:2014)
- Bone Implantation Test (ISO 10993-6:2007)

- Surface analysis (SEM/EDX) for the implants as required by FDA guidance *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*

- Evaluation of functional and mechanical properties, through a combination of physical testing and finite element analysis for implants and abutments:
  - Bending Compression Static and Fatigue Testing (ISO 14801:2007)
  - Torsional Testing are intended to determine the static torsion strength of hexagonal connection. The torsional testing is applicable to implants, clinic screws, cover screw, healing abutments and ball abutments and consists of applying an incremental torsional stress to the hexagonal connection until rupture and recording the rupture torque value (N.cm).
  - Retention Testing is intended to determine the retention force that occurs between the ball abutments and the different retention caps. The retention testing is applicable to ball abutments and consists of applying an incremental tension force on the ball abutment assembled with the retention caps until both components are dismounted. The retention testing also consists of 4000 mounting-dismounted cycles (1Hz) to determine the final retention force.

- Cleaning and Sterilization Testing (ISO 11137-1:2006, ISO 11137-2:2006, ISO 17665-1:2006 and ISO/TS 17665-2:2009)

- LAL Pyrogen Testing (USP 38-NF33:2015, <85>)

- Shelf Life Testing (ASTM F1980-07:2011):
  - Dye Testing (European Pharmacopoeia 3.2.9)
  - Sterility testing (ISO 11737-2:2009)

- Transport Testing (ASTM D4169-14)

10. Clinical Performance Data

None

11. Statement of Substantial Equivalence

Based on the similar intended use and the supporting non-clinical performance testing, the GMI Frontier Dental Implant System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device(s).