June 26, 2020

Medical Systems and Devices International Ltd.
% Iman Khorshid
CEO, Founder
QRS
Industrial Park Tefen
Tefen 2495900
ISRAEL

Re: K191443
Trade/Device Name: MSDI Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 21, 2020
Received: June 25, 2020

Dear Iman Khorshid:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K191443

Device Name
MSDI Dental Implants System

Indications for Use *(Describe)*
MSDI 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 or prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.
It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal 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 K191443

MSDI Dental Implants System

Applicant Name: Medical Systems and Devices International Ltd.
St. Ba'alei Malacha 26, P.O. Box 25414
Haifa, 3223020
ISRAEL
Tel: 972-54-932-0515

Establishment Registration Number: 3013167159

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Tel: 360-325-7028
Email: us.agent@mid-link.net

Date prepared: June 26, 2020

Trade Name: MSDI Dental Implants System

Classification name: Endosseous Dental Implant

Common/usual name: Dental Implant

Product Code: DZE, NHA

Regulation No.: 872.3640

Class: II

Panel identification: Dental Devices Panel

Description of the device:

MSDI Dental Implants System implants are self-tapping, root-form, two piece screw type dental implants, indicated for use in surgical and restorative applications for placement in the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function.

The MSDI's dental implant is a two stage screw type device that can equally well be used as one stage, surgically placed in the upper or lower jaw to provide support for prosthetic devices in partially or completely edentulous patients. The MSDI's implant is a two piece device to be used in combination with several different abutments and superstructures provided in order to aid in the prosthetic rehabilitation.

MSDI dental implants System is an internal hex implant system which provided in 3.3, 3.75, 4.2, 5.0 and 6.0 mm diameter for lengths of 8, 10, 11.5, 13 and 16mm. (There is no 6.0 mm diameter for the 16 mm length).

The MSDI Dental Implants are to be used in combination with cover screws, healing caps and abutments according to commonly used protocol in the dental implantation field.

The MSDI Dental Implants are made of Ti6AL4V ELI complying with standard ASTM F 136-13 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant.

The implants are grit blasted and acid etched surface. The system includes standard abutments, standard narrow abutments, standard shoulder abutments, standard wide shoulder abutments, multi- unit abutments, ball attachments, healing caps and standard 15° and 25° abutments are included in the system.

Indications for Use:

MSDI 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 or

prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Testing Summary:

Dynamic fatigue testing according to ISO 14801 was conducted to determine the abutments are strong enough for their intended use. Predicate device comparative testing was also provided. Surface analysis according to the FDA guidance document was done including SEM and EDS. Sterilization validation according to ISO 11137-1 and 11137-2 was conducted on the implants. Abutment steam sterilization validation was done according to ISO 17665-1 and ISO 17665-2. Package integrity testing according to ASTM F1929-12 and accelerated aging according to ASTM F1980-07 was conducted. Materials used in the product meet ASTM F136 and the biocompatibility was demonstrated by testing the cytotoxicity according to ISO 10993-5. Endotoxin testing according to USP 161 was conducted. Cleanliness of implants was tested according to ISO 19227.

Primary Predicate Device:

Spiral Dental Implants manufactured by GP Implants Ltd. cleared under 510(k) K162299.

Reference Device:

Alpha-Bio Tec Dental Implant System K063364

DSI Dental Implant System K200188

Substantial Equivalence:

Technological Characteristics

The MSDI Dental Implants System have the same intended use and principles of operation as GP Implants' Spiral Dental Implants cleared under 510(k) K162299 and have equivalent performance characteristics. The material used for the MSDI Dental Implants System, as well as the manufacturing methods, manufacturing site and subcontractor are the same as the predicate device.

Two differences exist between the subject device and primary predicate device:

The healing caps heights range, MSDI's healing caps 4.5 diameter in heights of 3,4,5,6 and 7mm and GP's healing caps 4.5 diameter in 2 and 7mm height.

MSDI's Implants system include three types of implants (Alef, TAF, KAF) and the predicate device include only one type of implant (SPI). The additional two types of implants (TAF and KAF) don't affect the intended use and indication for use since they are meant to be used the same way as the primary predicate device.

	MSDI Dental Implants System from Medical Systems and Devices International Ltd.	**Spiral Dental Implants from GP Implants Ltd.**	**Alpha-Bio Tec Dental Implant System**	**DSI Dental Implant System from DSI Dental Solutions Ltd.**
510(k) number	K191443	K162299	K063364	K200188
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Indications for Use	MSDI 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 or prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. It is intended for immediate loading when good primary	The Spiral Dental Implants is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support or prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved	The Alpha-Bio Tec 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. Alpha-Bio Dental	DSI Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patients esthetics and chewing function. DSI implants are intended for single or multiple unit restorations on

	MSDI Dental Implants System from Medical Systems and Devices International Ltd.	Spiral Dental Implants from GP Implants Ltd.	Alpha-Bio Tec Dental Implant System	DSI Dental Implant System from DSI Dental Solutions Ltd.
	stability is achieved and with appropriate occlusal loading.	and with appropriate occlusal loading.	Implant System is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	splinted or non-splinted applications. Premium Spiral implants are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period.
Supplied Sterile	Yes	Yes	Yes	Yes
Re-use	No	No	No	No
Material of Implants	Ti-6Al-4V, ELI	Ti-6Al-4V, ELI	Ti-6Al-4V, ELI	ASTM F136 Ti 6Al 4V ELI
Implants Shape	Screw type	Screw type	Screw type	Premium Spiral
Implants Connection	Internal Hexagon	Internal Hexagon	Internal Hexagon	Internal Hexagon
Implants Surface	Sand blasted and acid etched	Sand blasted and acid etched	Sand blasted and acid etched	Sand blasted and acid etched
Implants Length	8, 10, 11.5, 13 and 16mm	8, 10, 11.5, 13 and 16 mm	8, 10, 11.5, 13 and 16 mm	8, 10, 11.5, 13, 16 (6.0mm diameter not in 13 or 16 length)
Implants Diameter	3.3, 3.7, 4.2, 5.0 and 6.0 mm	3.3, 3.7, 4.2, 5.0, and 6.0 mm	3.3, 3.7, 4.2, 5.0, and 6.0 mm	3.5, 3.75, 4.2, 5.0, 6.0 mm
Abutments	Straight, 15° and 25°	Straight, 15° and 25°	Straight, 15° and 25°	Straight, 15° and 25°
Material of abutments	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI
Surface treatment of abutments	None	None	None	None

	MSDI Dental Implants System from Medical Systems and Devices International Ltd.	Spiral Dental Implants from GP Implants Ltd.	Alpha-Bio Tec Dental Implant System	DSI Dental Implant System from DSI Dental Solutions Ltd.
Types of abutments	Multi-unit abutments in heights of 1,2,3 and 4 mm	Multi-unit abutments in heights of 1,2,3 and 4 mm	AlphaLoc Attachment in heights of 0.5,1,2,3,4,5,6 and 7 mm	Multi-unit abutments in heights of 1,2,3 and 4 mm
	Ball attachments in heights of 1,2,3,4,5, and 6mm	Ball attachments in heights of 1,2,3,4,5, and 6mm	Ball attachments in heights of 0.5,2,3,4,5, and 6mm	Ball attachments in heights of 2,3,4,5, and 6mm
	Healing Caps 4.5 diameter in heights of 3,4,5,6 and 7mm	Healing Caps 4.5 diameter in 2 and 7mm height	Standard Healing Abutment in heights of 2,3,4,5,6 and 7mm	Healing Cap 3.8 in 3,4,5,6,7mm height
	Wide Healing Cap 5.5 diameter in heights 2,3,4,5,6 and 7mm	Healing Cap 5.5 diameter in heights 2,3,4,5,6 and 7mm	Wide healing abutment in heights of 3 and 5mm	Healing cap 4.6 and 5.5 in 2,3,4,5,6, and 7mm height. Healing Caps 6.3 in 2,3,4 and 5 mm height
	Standard Titanium Abutment with height of 7mm	Standard Titanium Abutment with height of 7mm	TLA with height of 8.5mm	4.5mm Standard Titanium Abutment with heights of 7,9, and 11 mm
	Standard narrow abutment with heights of 7,9, and 11mm	Standard narrow abutment with heights of 7,9, and 11mm	TLASP1 Height 8.9 TLASP2 Height 9.9 TLASP3 Height 10.9 TLASP4 Height 11.9	3.8mm Standard narrow abutment with heights of 7,9 and 11 mm
	Standard shoulder abutment in heights of 1,2,3 and 4mm	Standard shoulder abutment in heights of 1,2,3 and 4mm	ETLASP1 height 1 ETLASP1 height 2 ETLASP1 height 3 ETLASP1 height 4	4.5mm Standard shoulder abutment in heights of 1,2,3 and 4mm
	Standard Wide Shoulder Abutment with heights of 1,2,3 and 4mm	Standard Wide Shoulder Abutment with heights of 1,2,3 and 4mm	TLA02 height of 2 mm TLA04 height of 4 mm	5.4mm Standard Wide Shoulder Abutment with heights of 1,2,3 mm

	MSDI Dental Implants System from Medical Systems and Devices International Ltd.	Spiral Dental Implants from GP Implants Ltd.	Alpha-Bio Tec Dental Implant System	DSI Dental Implant System from DSI Dental Solutions Ltd.
	Standard 15° Abutment with heights of 8, 12, and 13mm	Standard 15° Abutment with heights of 8, 12, and 13mm	TLA15 height of 8.5mm TLAL15 height of 11.5mm	Standard 15° Abutment with heights of 1,2,3 mm
	Standard 25° Abutment with heights of 9 and 12mm	Standard 25° Abutment with heights of 9 and 12mm	TLA25 height of 8.5mm TLAL25 height of 11.5mm	Standard 25° Abutment with heights of 1,2,3 mm

Non-Clinical Performance Data

Fatigue test was performed according to ISO 14801 on the MSDI's dental implants and showed equivalence to the predicate devices.

The MSDI implants and abutments, as well as their predicate devices, are manufactured by the same sub-contractor "DAND" and manufactured in the same facility. Therefore, MSDI has adopted DAND's testing and validations in regard of all non- clinical DATA as it was adopted by the "GP Implants Ltd." the manufacturer of the predicate device.

Clinical Performance Data

No clinical performance data is provided in this submission.

Conclusion:

The evaluation of the MSDI's dental System is substantially equivalent to SPI Dental Implant System. They both have the same indications for use, are of the same material, have internal hex and connections. The abutments, healing caps, and angled abutments are offered in similar designs and heights. Performance testing demonstrates substantial equivalence to the identified predicate devices.