WARANTEC Company, Limited
% Peter Chung
Representative
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

June 18, 2018

Re: K172345
Trade/Device Name: IU Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 21, 2018
Received: May 24, 2018

Dear Peter Chung:

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 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K172345

Device Name
IU Implant System

Indications for Use *(Describe)*
The IU 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, and to restore the patient's chewing function.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary [as required by 807.92(c)]

I. SUBMITTER

a) Company: WARANTEC Co., Ltd.
b) Address: #411, #412, 474, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13229, Korea
c) Tel : +82-31-778-6328
d) Fax : +82-70-4324-6328
e) President of Company: Mr. Dong-Hwa Jang
f) Contact Person : Peter Chung, 412-687-3976
g) Contact Person Address: 300, Atwood Street, Pittsburgh, PA, 15213, USA
h) Date Prepared: June 16, 2018

II. DEVICE

a) Trade Name : IU Implant System
b) Common Name : Endosseous Dental Implant System
c) Classification Name : implant, endosseous, root-form
d) Product Code : DZE (primary), NHA (secondary)
e) Regulation Number : 872.3640
f) Class of device : Class II
g) Panel : Dental

III. PREDICATE DEVICE

a) Primary Predicate Device:
Luna Dental Implant System / SHINHUNG MST Co., Ltd. / K123155

b) Reference Device:
SuperLine / DENTIUM CO., LTD. / K160965
AnyOne^{TM} Internal Implant System / MegaGenImplant Co., Ltd. / K123988
Dentium Implantium® & SuperLine® Prosthetics / DENTIUM CO., LTD. / K141457
Dentium Implantium & SuperLine Prosthetics / DENTIUM CO., LTD. / K160828

IV. DEVICE DESCRIPTION

The IU Implant System is an integrated system of endosseous dental implants with corresponding various abutments (cover screw, two piece abutment, solid abutment, abutment screw, ball abutment, retained abutment, temporary abutment, and multi abutment).

The IU Implant System is a dental implant made of titanium metal intended to be

surgically placed in the bone of the upper or lower jaw arches.
There are two types of Fixtures, triangular screw threads design and square screw threads design. The IU Implant System includes the each fixtures is available in various diameters (lengths) 3.6 mm (8.5 mm, 10.0 mm, 11.5 mm, 13.0 mm) & 4.1 mm, 4.6 mm, 5.1 mm, 5.6 mm, 6.1 mm (7.5 mm, 8.5 mm, 10.0 mm, 11.5 mm, 13.0 mm) of triangular screw threads design and 4.3 mm, 4.8 mm, 5.3 mm (7.0 mm, 8.5 mm, 10.0 mm, 11.5 mm, 13.0 mm) & 6.3 mm (7.0 mm, 8.5 mm, 10.0 mm, 11.5 mm) of square screw threads design according to the anatomical situation. Fixture is made of pure titanium metal and supplied sterile. The surface is SA, Sandblasting and Acid etching, treated.
Abutment is device made of titanium alloy and it is intended for use to make permanent prostheses and/or temporary prosthesis. The abutments are provided non-sterile and should be sterilized before use.

V. INDICATIONS FOR USE

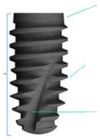
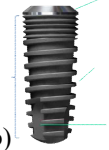
The IU Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

VI. SUBSTANIAL EQUIVALNECE COMPARISON

The IU Implant System is similar designs and dimensions, and has the same material, intended use, surface treatment and technological characteristics as the identified primary predicate device (K123155) and reference devices (K160965/K123988/ K141457). When compared with predicate device, no new questions of substantial equivalence have been raised for the IU Implant System.

Table 1 - Comparison of Endosseous Implant Characteristics

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**
510(k) Number	K172345	K123155	K160965	K123988
Manufacturer	WARANTEC Co., Ltd.	SHINHUNG MST Co., Ltd.	DENTIUM CO., LTD.	MegaGenImplant Co., Ltd.
Common Name	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System
Trade Name	IU Implant System	Luna Dental Implant System	SuperLine	AnyOne™ Internal Implant System
Device class	Class II	Class II	Class II	Class II
Product Code(s)	DZE	DZE	DZE	DZE
Indications for Use/ Intended Use	The IU Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to	The Luna Dental Implant System is intended to be surgically placed in the bone of the upper or	SuperLine is indicated for use in surgical and restorative applications for placement in the bone of the upper or	The AnyOne ™ Internal Implant System is intended to be surgically placed in the maxillary or

	provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.	lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.	lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. SuperLine is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 06.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Implant design	Root-form endosseous dental implants	Implant, Endosseous, Root-Form	Root-form endosseous dental implants	Root-form endosseous dental implants
Shape	a)  , b) 			
Connection	2.1, 2.5 Internal Hex	2.1, 2.5 Internal Hex	Internal Hex	Internal Hex
Diameter of fixture	a) 3.6, 4.1, 4.6, 5.1, 5.6, 6.1 mm b) 4.3, 4.8, 5.3, 6.3 mm	3.7, 4.2 – 5.7 mm	3.6, 4.0, 4.4, 4.9, 6.0, 7.0 mm	Internal type 3.9, 4.3, 5.3, 6.3, 7.3 mm (for normal thread) 4.8, 5.8, 6.8, 7.8, 8.3 mm (for deep thread) 4.8, 5.3, 6.3, 7.3 mm (for special length)
Length of fixture	a) 7.5, 8.5, 10.0, 11.5, 13.0 mm (cf. 3.6 mm diameter does not include a 7.5 mm length.)	8.5 – 15.0 mm	7.0, 8.0, 10.0, 12.0, 14.0 mm	Internal type 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm (for normal and deep thread)

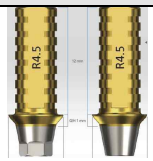
	b) 7.0, 8.5, 10.0, 11.5, 13.0 mm (cf. 6.3 mm diameter does not include a 13.0 mm length.)			7.0 mm (for special length)
Material	Pure titanium (ASTM F67)	Pure titanium (ASTM F67)	Pure titanium (ASTM F67)	Pure titanium (ASTM F67)
Physical testing performed	Not tested/no angulation submitted for clearance.	Test according to ISO 14801	Test according to ISO 14801	Test according to ISO 14801
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1
Surface treatment	S.L.A	S.L.A	S.L.A	S.L.A
Sterilization method	Gamma radiation	Gamma radiation	Gamma radiation	Gamma sterilization
Shelf-life	7years	-	8years	-

Table 2 - Comparison of Endosseous Abutments Characteristics

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**
510(k) Number	K172345	K123155	K141457	K123988
Manufacturer	WARANTEC Co., Ltd.	SHINHUNG MST Co., Ltd.	DENTIUM CO., LTD.	MegaGenImplant Co., Ltd.
Common Name	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System
Trade Name	IU Implant System	Luna Dental Implant System	Dentium Implantium® & SuperLine® Prosthetics	AnyOne™ Internal Implant System
Device class	Class II	Class II	Class II	Class II
Product Code(s)	NHA	NHA	NHA	NHA
Indications for Use	The IU 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, and to restore the patient's chewing function.	The Luna 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, and to restore the patient's chewing function.	Dentium Implantium® & SuperLine® Prosthetics are intended for use as an aid in prosthetic rehabilitation.	The AnyOne ™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller

	Subject Device	Primary Predicate Device	Reference Device	Reference Device
510(k) Number	K172345	K123155	K141457	K123988
				implants (less than 06.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Cover Screw				
Shape				
Material	Pure titanium (ASTM F67)	Pure titanium (ASTM F67)	Ti-6A1-4V-ELI (ASTM F136)	CP4 Titanium (ASTM F67)
Diameter	2.82, 3.32 mm	-	3.6 mm	-
Abutment Screw				
Shape				
Material	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Ti-6A1-4V-ELI
Diameter	2.2 mm	-	1.8 ~ 2.3 mm	3.8 ~ 10.0 mm

	Subject Device	Primary Predicate Device	Reference Device	Reference Device
510(k) Number	K172345	K123155	K160828	K123988
Manufacturer	WARANTEC Co., Ltd.	SHINHUNG MST Co., Ltd.	DENTIUM CO., LTD.	MegaGenImplant Co., Ltd.
Common Name	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System
Trade Name	IU Implant System	Luna Dental Implant System	Dentium Implantium® & SuperLine® Prosthetics	AnyOne™ Internal Implant System
Device class	Class II	Class II	Class II	Class II
Product Code(s)	NHA	NHA	NHA	NHA
Indications for Use	The IU Implant System is intended to be surgically placed in	The Luna Dental Implant System is intended to be	Dentium Implantium® & SuperLine® Prosthetics are	The AnyOne ™ Internal Implant System is intended to

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**
510(k) Number	K172345	K123155	K160828	K123988
	the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.	surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.	intended for use as an aid in prosthetic rehabilitation.	be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 06.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Temporary Abutment				
Shape	 (Hex) (Non-Hex)	 (Hex) (Non-Hex)	 (Hex) (Non-Hex)	
Material	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Pure Titanium Grade 5 (ASTM F67)	Ti-6A1-4V-ELI
Diameter	3.9 mm	4.0 ~ 6.0 mm	4.5 mm	3.8 ~ 10.0 mm
Two Piece Abutment				
Shape	 (Hex)	 (Hex) (Non-Hex)	 (Hex) (Non-Hex)	 (Hex) (Non-Hex)

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**
510(k) Number	K172345	K123155	K160828	K123988
	 (Hex) (Non-Hex)			
Material	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Pure Titanium Grade 5 (ASTM F67)	Ti-6A1-4V-ELI
Diameter	3.8, 4.5, 5.5 mm 3.95, 4.95, 5.95 mm	4.0 ~ 6.0 mm	4.5, 5.5, 6.5 mm	3.8 ~ 10.0 mm
Solid Abutment				
Shape				
Material	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Pure Titanium Grade 5 (ASTM F67)	Ti-6A1-4V-ELI
Diameter	3.8, 4.95, 5.5 mm 3.95, 4.95, 5.95 mm	4.0 ~ 6.0 mm	4.5, 5.5, 6.5 mm	3.8 ~ 10.0 mm
Healing Abutment				
Shape				
Material	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Pure Titanium Grade 5 (ASTM F67)	Ti-6A1-4V-ELI
Diameter	3.95, 4.95, 5.95 mm	4.0 ~ 6.0 mm	4.0, 4.5, 5.5, 6.5 mm	3.8 ~ 10.0 mm
Height	9.0, 10.0, 11.0, 12.0, 13.0 14.0 mm	8.5 ~ 15.0 mm	8.2~14.6mm	7.7 ~ 18.7 mm
Ball Abutment				
Shape				-
Material	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Pure Titanium Grade 5 (ASTM F67)	Ti-6A1-4V-ELI
Diameter	4.3 mm	4.0 ~ 6.0 mm	3.3, 3.5 mm	3.8 ~ 10.0 mm
Multi Abutment				
Shape				

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**
510(k) Number	K172345	K123155	K160828	K123988
Material	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Pure Titanium Grade 5 (ASTM F67)	Ti-6A1-4V-ELI
Diameter	4.95 mm	4.0 ~ 6.0 mm	4.5, 5.5 mm	3.8 ~ 10.0 mm
Retained Abutment				
Shape		-		-
Material	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Ti-6A1-4V-ELI (ASTM F136)	Ti-6A1-4V-ELI (ASTM F136)
Diameter	4.3 mm	4.0 ~ 6.0 mm	3.7mm	3.8 ~ 10.0 mm
Height	8.4, 8.4, 9.4, 9.5, 10.4, 10.5, 11.4, 11.5, 12.4, 12.5, 13.4, 13.5 mm	8.5 ~ 15.0 mm	7.7~12.1mm	7.7 ~ 18.7 mm
Physical testing performed	Not tested/no angulation submitted for clearance.	Test according to ISO 14801	Test according to ISO 14801	Test according to ISO 14801
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1
Sterilization method	Non-sterile (Steam sterilization prior to use).	Non-sterile (Steam sterilization prior to use).	Non-sterile (Steam sterilization prior to use).	Non-sterile (Steam sterilization prior to use).

VII. NON-CLINICAL TEST DATA

The results of the non-clinical testing demonstrate that the results have met the criteria of the standards, and the subject device is substantially equivalent to the predicate device. This testing included:

Biocompatibility testing

The biocompatibility evaluation for the IU Implant System was conducted in accordance with the International Standard ISO 7405:2008, "Dentistry – Evaluation of biocompatibility of medical devices used in dentistry", ISO 10993-1:2009/AC:2010, "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing" as recognized by FDA.

- Cytotoxicity (Elusion)
- Sensitization
- Oral irritation
- Systemic Toxicity (acute)
- Genotoxicity
- Implantation

- Endotoxin Test (LAL test)

The USP <85> test method will be used to evaluate pyrogen limit specifications for the subject device. The endotoxin testing will be conducted on every batch for the subject device and the testing limit will be below 5 EU/mL. We referenced the USP 39 <85> to device on the endotoxin limit which is 5 EU/mL.

Sterilization Testing

Sterilization validating testing has been performed in accordance with ISO 11137-1:2006/Amd.1:2013, ISO 11137-2:2013 and ISO 11137-3:2006 for gamma sterilization and ISO 17665-1 and ISO 17665-2 for steam sterilization. Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Shelf Life Testing

For the subject devices provided sterile, accelerated aging shelf life testing was conducted according to ASTM F1980; real time testing is being conducted to support accelerated aging results.

Risk Analysis

Risk analysis for IU Implant System was conducted in accordance with ISO 14971, Medical Devices: Application of Risk Analysis, for medical devices. It was determined by IU Implant System that all risks associated with IU Implant System were acceptable and as low as reasonably possible.

No clinical data were included in this submission.

VIII. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification WARANTEC Co., Ltd. concludes that the SHINHUNG MST Co., Ltd., DENTIUM CO., LTD., and MegaGenImplant Co., Ltd. is substantially equivalent to the predicate devices as described herein.