HOOWON EDI Co., Ltd
℅ Sanglok Lee
Manager
Wise Company Inc.
#507, #508, 166 Gasan digital 2-ro, Geumcheon-gu
Seoul, Seoul 08503
REPUBLIC OF KOREA

May 24, 2024

Re: K231426
Trade/Device Name: 8plant Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 24, 2024
Received: April 24, 2024

Dear Sanglok Lee:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231426

Device Name
8plant Implant System

Indications for Use *(Describe)*

8plant Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implant bodies with a diameter of 5mm or more are intended to be used in the molar region.

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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K231426

510(k) Summary

Date revised: May 24, 2024

01. Applicant / Submitter

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02. Submission Correspondent

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03. Proposed Device Identification

Trade Name: 8plant Implant system
Classification Name: Implant, Endosseous, Root-Form
Common Name: Endosseous Dental Implant
Device Class: Class II
Regulation Number: 21 CFR 872.3640
Primary Product Code: DZE
Secondary Product Code: NHA
Review Panel: Dental

04. Indication for use

8plant Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implant bodies with a diameter of 5mm or more are intended to be used in the molar region.

05. Predicate Device Identification

Primary Predicate Device

K Number	Manufacturer	Trade Name
K211090	Izenimplant Co., Ltd.	ZENEX Implant System

Reference Devices

K Number	Manufacturer	Trade Name
K122231	MegaGen Implant Co., Ltd.	Xpeed AnyRidge Internal Implant System
K210134	Dentis Co., Ltd.	Dentis s-Clean s-Line
K210161	MegaGen Implant Co., Ltd.	AnyOne Onestage Implant System

06. Device Description

8plant Implant System consists of SF Fixtures, Cover Screw, Abutment, and Abutment Screw.

1) 8plant Implant System (SF Fixtures and Cover Screw)

This titanium dental implant features a SLA (Sandblasted with Large-grit and Acid-etched) surface with the alveolar bone and is designed to support single or multiple-unit restorations in partially or fully edentulous patients. It is secured to the upper structure using an internal hex fastening system.

2) 8plant Abutment System (Abutment and Abutment Screw)

8plant Abutment System is compatible with the SF Fixtures. 8plant Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. The 8plant Abutment System consists of the following;

Healing Abutment	Healing is used during the healing period prior to restorations and maintain the shape of the gum.
Rigid Abutment	It is a one-body product that consists of a support column and a screw integrally, and the implant fixture and the 11° taper angle body taper face meet and are used.
Locator Abutment	Locator Abutment is a product that is located inside and acts as a support when manufacturing Overdenture through an implant fixture.
Transfer Abutment	It is an abutment used when manufacturing screw retaining prosthesis in multiple cases.
Angled Abutment	It is an abutment used when manufacturing screw retaining prosthesis in multiple cases.
Temporary Abutment	Temporary Abutment is used by removing the healing abutment as an abutment for making temporary prostheses.
Abutment Screw	It is used to fix the abutment to the fixture.

7. Substantial Equivalence Comparison

Dental Implant System has the same intended uses, principle of operation and similar technical characteristics and functionality as predicate device and reference devices.

1) Fixture and Cover Screw

1-1) Fixture

	Subject Device	Predicate Device	Reference Device
Manufacturer	HOOWON EDI Co., Ltd.	Izenimplant Co., Ltd.	MegaGen Implant Co., Ltd.
Device Name	8palnt Implant System	ZENEX Implant System	Xpeed AnyRidge Internal Implant System
510(k) Number	K231426	K211090	K122231
Product Code / Regulation No.	DZE / 21CFR 872.3640	DZE / 21CFR 872.3640	DZE / 21CFR 872.3640
Classification	Class II	Class II	Class II
Indications for Use	8 plant Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implant bodies with a diameter of 5mm or more are intended to be used in the molar region.	ZENEX Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.	The Xpeed AnyRidge 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 implants (less than Ø 6.0 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.
Structure	- Internal Hex connected - Submerged Fixture - Straight/Taper body shape	- Internal Hex connected - Submerged Fixture - Straight/Taper body shape	- Internal Hex connected - Submerged Fixture - Straight/Taper body shape
Body Diameter(ø) and Length (mm)	Ø3.75 x L 8.5, 10, 11.5, 13 Ø4.25 x L7, 8.5, 10, 11.5, 13 Ø4.6 x L7, 8.5, 10, 11.5, 13 Ø5.05 x L7, 8.5, 10, 11.5, 13 Ø5.6 x L7, 8.5, 10, 11.5, 13 Ø6.2 x L7, 8.5, 10, 11.5, 13 Ø7.1 x L7, 8.5, 10, 11.5, 13	Mini Ø 3.75 x L8.5, 10, 11.5, 13, 15 Regular Ø 4.25 x L7, 8.5, 10, 11.5, 13,15 Ø 4.6 x L7, 8.5, 10, 11.5, 13, 15 Wide Ø 5.05 x L7, 8.5, 10, 11.5, 13, 15 Ø 5.4 x L7, 8.5, 10, 11.5, 13 Ø 5.9 x L7, 8.5, 10, 11.5, 13	Normal thread Ø4.0 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø4.4 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø4.9 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø5.4 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Ø5.9 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 Deep thread Ø6.4 X 7.9, 9.4, 10.9, 12.4, 14.4 Ø6.9 X 7.9, 9.4, 10.9, 12.4, 14.4

		Ø 6.75 x L7, 8.5, 10, 11.5, 13	Ø7.4 X 7.9, 9.4, 10.9, 12.4, 14.4 Ø7.9 X 7.9, 9.4, 10.9, 12.4, 14.4 Ø8.4 X 7.9, 9.4, 10.9, 12.4, 14.4
Material	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Surface Treatment	Sandblasted and acid-etched	Sandblasted and acid-etched	Sandblasted and acid-etched
Sterilization	Gamma	Radiation	Radiation
Shelf life	2 years	5 years	5 years
Similarities	The subject device has the same device characteristics with the predicate device such as diameters, length, intended use, material, principle of operation, connection design, design, structure and sterilization method.		
Differences	The diameter of the subject device includes Ø 7.1 that is slightly bigger than the primary predicate. To support this difference, K122231 is added as a reference device to support the difference in diameter. As the subject device doesn't categorize the fixture size into 'Mini, Regular, and Wide' like the predicate device, we have removed the phrase related to the Wide Fixture System and revised it as follows: Implant bodies with a diameter of 5mm or more are intended to be used in the molar region.		

1-2) Cover Screw

		Subject Device	Predicate Device
Manufacturer		HOOWON EDI Co., Ltd.	Izenimplant Co., Ltd.
Device Name		8palnt Implant System	ZENEX Implant System
510(k) Number		K231426	K211090
Product Code / Regulation No.		DZE / 21CFR 872.3640	DZE / 21CFR 872.3640
Classification		Class II	Class II
Design			
Connection Type		Non-Hex	Non-Hex
Dimension	D(ø)	3.1 3.58	3.0 ~ 3.9
	Length(mm)	5.1 ~ 5.9	5 ~ 7.3
	Angle(°)	0	0
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface Treatment		No Treatment	No Treatment

Sterilization	End User Sterilization	Gamma
Shelf life	Non-shelf Life	5 years
Similarities	The subject device has the same device characteristics with the predicate device such as diameters, length, intended use, material, principle of operation, connection design, design, structure and surface treatment method.	
Differences	The subject device's sterilization is End User Sterilization, which is different from the predictive Device. Sterilization validation has been conducted to support this difference.	

2) Abutment and Abutment Screw

2-1) Healing Abutment

		Subject Device	Predicate Device
Manufacturer		HOOWON EDI Co., Ltd.	Izenimplant Co., Ltd.
Device Name		8palnt Implant System	ZENEX Implant System
510(k) Number		K231426	K211090
Product Code / Regulation No.		DZE / 21CFR 872.3640	DZE / 21CFR 872.3640
Classification		Class II	Class II
Design			
Connection Type		Non-Hex	Non-Hex
Dimension	D(ø)	4.3,4.8,5.3,5.8,6.3,7.3,8.3	4.3 ~ 9.0
	G/H(mm)	1.0 ~ 12.0	2.0 ~ 9.0
	Angle(°)	0	0
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface Treatment		No Treatment	No Treatment
Sterilization		End User Sterilization	Gamma
Shelf life		Non-shelf Life	5years
Similarities		The subject device has the same device characteristics with the predicate device such as intended use, material, connection design, design, structure and surface treatment method.	
Differences		G/H of subject device is slightly larger than the Predictive Device. This discrepancy is not critical to the device. The subject device's sterilization is End User Sterilization, which is different from the predictive Device. Sterilization validation has been conducted to support this difference.	

2-2) Rigid Abutment

		Subject Device	Reference Device
Manufacturer		HOOWON EDI Co., Ltd.	Dentis Co., Ltd.
Device Name		8palnt Implant System	Dentis s-Clean s-Line
510(k) Number		K231426	K210134
Product Code / Regulation No.		DZE / 21CFR 872.3640	DZE / 21CFR 872.3640
Classification		Class II	Class II
Design			
Connection Type		Non-Hex	Non-Hex
Dimension	D(ø)	4.0~7.0	4.5~6.5
	P/H(mm)	4.0,5.5,7.0	-
	Angle(°)	0	0
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface Treatment		No Treatment	No Treatment
Sterilization		End User Sterilization	End User Sterilization
Similarities		The subject device has the same device characteristics with the predicate device such as diameters, Length, intended use, material, principle of operation, connection design, design, structure, surface treatment and sterilization method.	
Differences		The subject's P/H contains P/Hs that are not supported by the reference device, K210134. This discrepancy is not critical to the device.	

2-3) Locator Abutment

	Subject Device	Reference Device
Manufacturer	HOOWON EDI Co., Ltd.	MegaGen Implant Co., Ltd.
Device Name	8palnt Implant System	AnyOne Onestage Implant System
510(k) Number	K231426	K210161
Product Code / Regulation No.	DZE / 21CFR 872.3640	DZE / 21CFR 872.3640
Classification	Class II	Class II

Design			
Connection Type		Non-Hex	Non-Hex
Dimension	D(ø)	3.87,4.0	3.89
	G/H(mm)	0.84~5.84	0.3,0.8,1.8,2.8,3.8,4.8,5.8,6.8
	Angle(°)	0	Up to 20°
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface Treatment		No Treatment	Partial TiN coated
Sterilization		End User Sterilization	Non-Sterile
Similarities		The subject device has the same device characteristics with the predicate device such as diameters, length, intended use, material, principle of operation, connection design, design, structure and method.	
Differences		The diameter of the subject device is slightly larger than that of the reference device, K210161. This difference does not affect the basic functionality of the device. Sterilization validation has been conducted.	

2-4) Transfer Abutment

	Subject Device	Predicate Device	Reference Device
Manufacturer	HOOWON EDI Co., Ltd.	Izenimplant Co., Ltd.	Dentis Co., Ltd.
Device Name	8palnt Implant System	Cemented Abutment	Dentis s-Clean s-Line
510(k) Number	K231426	K211090	K210134
Product Code / Regulation No.	DZE / 21CFR 872.3640	DZE / 21CFR 872.3640	DZE / 21CFR 872.3640
Classification	Class II	Class II	Class II
Design			
Connection Type	Hex	Hex	Hex

Dimension	D(ø)	4.0,4.5,5.0,5.5,6.0,6.5,7.0	4.5 ~ 6.5	4.5, 5.5, 6.5
	P/H(mm)	4.0,5.5,7.0	4.0~7.0	-
	Angle(°)	0	0	0
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface Treatment		No Treatment	Partial TiN coated in upper	No Treatment
Sterilization		End User Sterilization	Non-Sterile	End User Sterilization
Similarities		The subject device has the same device characteristics with the predicate device such as diameters, length, intended use, material, principle of operation, connection design, design, structure and method.		
Differences		The diameters of the subject device include Ø 4.0 and Ø 7.0 which are slightly smaller or larger than the predicate device. This difference does not affect the basic functionality of the device. Sterilization validation has been conducted.		

2-5) Angled Abutment

		Subject Device	Predicate Device
Manufacturer		HOOWON EDI Co., Ltd.	Izenimplant Co., Ltd.
Device Name		8palnt Implant System	Angled Abutment
510(k) Number		K231426	K211090
Product Code / Regulation No.		DZE / 21CFR 872.3640	DZE / 21CFR 872.3640
Classification		Class II	Class II
Design			
Connection Type		Hex	Hex, Non-Hex
Dimension	D(ø)	4.0,4.5,5.0,6.0	4.5, 5.5, 6.5
	G/H(mm)	0.8,1.8,2.8,3.8	2.8, 3.8
	Angle(°)	17	15, 25
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface Treatment		No Treatment	Partial TiN coating
Sterilization		End User Sterilization	Non-Sterile
Similarities		The subject device has the same device characteristics with the predicate device such as diameters, length, intended use, material, principle of operation, connection design, design, structure and sterilization method.	
Differences		The diameter of the subject contains Ø4.0, slightly smaller than the reference device, K211090 This is discrepancy is not critical to	

	the device. Sterilization validation has been conducted.

2-6) Temporary Abutment

		Subject Device	Predicate Device
Manufacturer		HOOWON EDI Co., Ltd.	Izenimplant Co., Ltd.
Device Name		8palnt Implant System	ZENEX Implant System
510(k) Number		K231426	K211090
Product Code / Regulation No.		DZE / 21CFR 872.3640	DZE / 21CFR 872.3640
Classification		Class II	Class II
Design			
Connection Type		Hex	Hex, Non-Hex
Dimension	D(ø)	4.0, 4.6	4.0,4.5
	P/H(mm)	10	10
	Angle(°)	0	0
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface Treatment		No Treatment	Non-Coating
Sterilization		End User Sterilization	Non-Sterile
Similarities		The subject device has the same device characteristics with the predicate device such as diameters, length, intended use, material, principle of operation, connection design, design, structure and method.	
Differences		The diameter of the subject is slightly larger than that of the predict Device. This difference does not affect the basic functionality of the device. Sterilization validation has been conducted.	

2-7) Abutment Screw

	Subject Device	Reference Device
Manufacturer	HOOWON EDI Co., Ltd.	Dentis Co., Ltd.
Device Name	8palnt Implant System	Dentis s-Clean s-Line
510(k) Number	K231426	K210134
Product Code / Regulation No.	DZE / 21CFR 872.3640	DZE / 21CFR 872.3640
Classification	Class II	Class II

Design			
Connection Type		Hex	Hex
Dimension	D(ø)	2.1,2.2,2.3,2.5,2.9	2.32
	Length(mm)	3.75,8.0,8.35,10.2	9.4
	Angle(°)	0	0
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)
Surface Treatment		No Treatment	Non-Coating
Sterilization		End User Sterilization	End User Sterilization
Similarities		The Subject device has the same device characteristics with the predicate device such as diameters, length, intended use, material, principle of operation, connection design, design, structure, surface treatment and sterilization method.	
Differences		The diameter of the subject device includes Ø 2.5,2.9 that is slightly bigger than the reference device, K210134. This discrepancy is not critical to the device.	

08. Non-clinical Test

Bench tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The results of the below tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.
The test results demonstrated that the subject device complies with the following standards:

▪ **Mechanical Performance**
- Fatigue testing for 8plant Implant system was conducted according to the “Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment” and “ISO 14801:2016 Dentistry - Fatigue test for Endosseous dental implants” under the worst case scenario.

▪ **Surface Analysis**
Surface modification testing, utilizing EDS and SEM evaluations was conducted across multiple lots to demonstrate consistency and appropriateness of the S.L.A. treated implant surface according to the “Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.”

▪ **Sterilization, Shelf-life and Packaging for Sterile Product**
- Gamma sterilization validation according to ISO 11137-1: 2006+A2:2018, ISO 11137-2:2013 and ISO 11137-3:2017

- End User Sterilization Validation according to ISO 11138-1:2017, ISO 11138-3:2017, ISO 17665-1:2006, ISO/TS 17665-2:2009, ISO 11737-1:2018 and ISO 11737-2:2019
- Real time aging test according to ASTM F88, ASTM F1929

▪ **MR Environment Condition**
Non-clinical worst-case MRI review was performed to evaluate the subject device components in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” including magnetically induced displacement force and torque.

▪ **Bacterial Endotoxin**
The subject device will not be labeled as "non-pyrogenic", and the endotoxin testing will be conducted on every batch for the subject device with the testing limit of below 0.5 EU/mL in accordance with the USP <85> "Bacterial Endotoxins Test.

▪ **Biocompatibility**
Biocompatibility evaluations according to ISO 10993-1 and Biocompatibility according to ISO 10993-5, ISO 10993-12.

09. Substantial Equivalence Conclusion

The subject device has the same indications for use and technological characteristics, as the above identified predicate and reference devices. A predicate device for each difference was presented, similarities and differences were addressed and discussed.
Based upon the comparison and information described above, HOOWON EDI Co., Ltd. has concluded that the 8plant Implant system is substantially equivalent to the discussed primary predicate and reference devices.