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

May 9, 2016

InnoBioSurg Co., Ltd.
c/o Ms. April Lee
Consultant
Withus Group Inc.
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K153350
Trade/Device Name: IBS Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 1, 2016
Received: April 8, 2016

Dear Ms. 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 (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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

IBS implant
Innobiosurg Co.,Ltd

InnoBioSurg Co., Ltd.
44-19, Techno 10-ro, Yuseong-gu, Daejeon, 305-510, Korea
Tel. 82- 42-933-2879 / Fax. 82-42-933-2881

Indication for Use

510(K) Number (if known): K153350

Device Name: IBS Implant System

Indication for Use:

The IBS Implant System is intended to replace missing teeth to restore chewing function. The IBS Implant can be placed in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.

Prescription Use ____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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510(k) Summary

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Device Information

- Trade Name: IBS Implant System
- Common Name: Dental Implant System
- Classification Name: Endosseous dental implant
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date prepared: 5/2/2016

General Description

An endosseous dental implant is a device made of a material such as Ti-6AL-4V Eli (Conforming to ASTM Standard F-136). The IBS Implant System is consists of dental implants, abutments, and screws for use in one or two-stage dental implant placement and restorations. The implant-abutment connection is tight and precise fitting with internal hex and Morse taper bevel.
The surface of the system has been treated with RBM (Resorbable Blasted media) to increase junction strength by increasing the area of bone-implant interface.

There are 2 types of fixtures in this system, NR Fix and Magic FC.
The NR Fix has diameters in 3.5mm and lengths in 9, 10, 11, 12, 13, 14 mm.
The Magic FC has diameters in 4, 4.5, 5.0, 5.5, 6.0, 6.5mm and lengths in 7, 9, 11, 13, 15 mm.

The contained various abutments and accessories in the system are Magic Screw, Screw retained type Abutment & protect cap, Healing Abutment, Angled Abutment (hexa, non hexa), Pair Abutment (non hexa), Solid Abutment & Solid abutment cap, Magic abutcoping (transfer type, pick up type), Multiunit abutment, UCLA abutment.
Fixtures and abutments are packaged separately. The Fixtures are supplied sterile and the abutments and accessories are provided non-sterile. The abutments and accessories should be sterilized before use. But healing abutment is supplied sterile.

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The purpose of this submission is to add new fixtures (NR Fix, Magic FC), magic screw, healing abutment, angled abutment, pair abutment (non-hexa), screw retained type abutment, solid abutment and solid abutment cap, magic abutcoping, UCLA abutment, and Multi unit abutment. Also, the shelf life of the products is changed from 2 years to 5 years.

Indication for Use

The IBS Implant System is intended to replace missing teeth to restore chewing function. The IBS Implant can be placed in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.

Materials:

The dental implants are fabricated fromTi-6AL-4V Eli (Conforming to ASTM Standard F-136).

Non-Clinical Data:

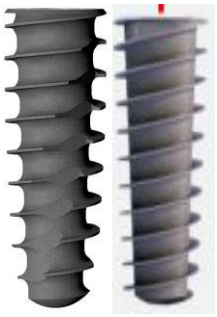
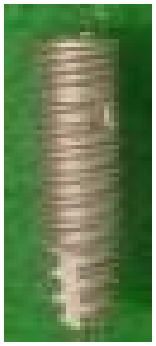
Non-clinical tests followed the recommendations in the “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant abutments”. Sterilization Validation testing performed in accordance with ISO 11137-1:2006, ISO 11137-2:2009 and surface treatment analysis were used to support the decision of substantial equivalence. Fatigue test was performed under the worst case scenario in accordance with ISO 14801:2007.

Comparison to Predicate Devices:

Comparison of the technological characteristics of the subject device and predicate devices is shown in the Table of Substantial Equivalence below.

1) Fixture

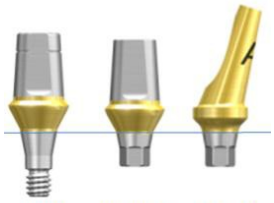
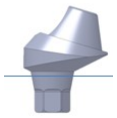
- K140806, IBS Implant System by InnoBioSurg Co., Ltd.

	Subject Device	Predicate Device
Product Name	IBS Implant System	IBS Implant System
510(k) **Product code** **Class**	NA DZE II	K140806 DZE II
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Indication for use	The IBS Implant System is intended to replace missing teeth to restore chewing function. The IBS Implant System can be placed in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.	The IBS Implant System is intended to replace missing teeth to restore chewing function. The IBS Implant System can be placed in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures and not for immediate loading. This system is intended for delayed loading.
Design	 NR Fix  Magic FC	
Composition of Material	Titanium Alloy Ti-6Al-4V Eli ASTM F136	Titanium Alloy Ti-6Al-4V Eli ASTM F136
Fixture Type	Submerged	Submerged
Endosseous Implant	Tapered, macro threads	Tapered, macro and micro threads

Components	Various abutments and accessories	Various abutments and accessories
Range of Diameters (mm)	NR Fix : 3.5mm Magic Fc : 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 mm	3.8, 4.3, 4.8, 5.3, 5.8, 6.3 mm
Range of Lengths (mm)	NR Fix : 9, 10, 11, 12, 13, 14mm Magic FC : 7, 9, 11, 13, 15mm	7 mm – 15 mm
Modified Surface	R.B.M.	R.B.M.
Surgical Technique	1 stage and 2 stage, self tapping	1 stage and 2 stage, self tapping
Gamma Sterilization	Yes	Yes

2) Abutments

- K140507, Hiossen Prosthetic System by Osstem Implant Co., Ltd.
- K123755, Multi Angled Abutment by Osstem Implant Co., Ltd.
- K111120, CSM Submerged-R Implant System by CSM Implant

	Subject Device	**Predicate devices**		
		Hiossen Prosthetic System	**Multi Angled Abutment**	**CSM Submerged-R Implant System**
Manufacturer	Innobiosurg Co., Ltd	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	CSM Implant
Design	 pair angled solid			
	 Multiunit			

	 UCLA			 UCLA
510(k) No.	-	**K140507**	**K123755**	**K111120**
Intended Use	IBS prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Hiossen Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Multi Angled Abutment is intended for use a dental implant to provide support for prosthetic restoration such as crowns, bridges, or overdentures.	The CSM Submerged-R implant system is especially designed for use in dental implant surgery.
Structure	Internal Hex	External Hex	External Hex	Internal Hex
Connection Type	Internal Hex-Connected	Screw & External Hex-Connected	Screw & External Hex-Connected	Internal Hex-Connected
Diameter (mm)	Solid:3.5/4.0/4.5/5.0/5.5/6.0/6.5 Pair:4.0/4.5/5.0/5.5/6.0/6.5 Angled:4.0/4.5/5.0 UCLA:3.5/4/4.5/5/5.5 Multiunit:4.1/4.5/5.0/5.5/6.0/6.5 Screw retained type:3.5/4.0/4.5/5.5/6.5	Rigid : 4.0/4.6/5.0/6.0/7.0/8.0 Transfer : 4.0/4.6/5.0/6.0/7.0/8.0 Angled : 4.0/4.3/4.5/4.8/5.5/6.0	Multi Angle : -	UCLA:4.5
G/H Length (mm)	Solid:1.0/2.0/3.0/4.0 Pair: 1.0/2.0/3.0/4.0 Angled: 1.0/2.0/3.0/4.0 UCLA: 1.0/2.0/3.0/4.0 Multiunit: 1.0/2.0/3.0/4.0/5.	Rigid : 0.5/1.0/2.0/2.5/3.0/4.0/5.0 Transfer : 0.5/1.0/2.0/2.5/3.0/4.0/5.0 Angled : 0.5/1.0/2.0 / 2.5 / 3.0 / 4.0	Multi Angle : -	UCLA:0.75

	0 Screw retained type:0.7/1.5/2.5/3.5/4.5/5.5/6.5			
Post Length (mm)	Solid:4.0/6.0/8.0 Pair:6.0 Angled:0,1.0/2.0/3.0/4.0 UCLA:1.0/2.0/3.0/4.0	Rigid : 4.0/5.5/7.0 Transfer : 4.0/5.5/7.0/8.0 Angled : -	Multi Angle : -	UCLA:12
Angle(°)	Angled : 15°/25°/30° Multi Angel : 17°/30°	Angled : 17° / 25°	Multi Angle : 17°/30°	-
Material of Abutment	Titanium Alloy (ASTM F 136) Polydiacetate: Cap, UCLA Titanium Gr4 (ASTM F67) : Multiunit abutment cap	Titanium Alloy (ASTM F 136) : Rigid, Transfer, Angled, Convertible	Titanium Alloy (ASTM F 136) :	P.O.M(UCLA)
Surface	Machine	Machine or TiN	Machine	Machine
Sterilization	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile

Substantial Equivalence Discussion

The IBM Implant System has a substantially equivalent intended use as the identified predicates. The subject device is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments, and they are all constructed of titanium.

The subject and predicate devices are similar in indications, design, technology, functions, dimensions and materials.

The subject device and predicate have slightly different Indications for Use language. However, the difference in language does not change the intended use or substantial equivalence. The differences between the subject device and predicate devices are slight differences in fixture's design and sizes. Differences in technological characteristics do not raise different questions of safety and effectiveness compared to the predicate device.

Conclusion

The IBS Implant System, subject device of this submission, constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, IBS Implant System and its predicate are substantially equivalent.