DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 15, 2017

InnoBioSurg Co., Ltd.
% April Lee
Consultant
Withus Group Inc
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K162099
Trade/Device Name: IBS Implant System II
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 10, 2017
Received: January 17, 2017

Dear April 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,

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)*
K162099

Device Name
IBS Implant System II

Indications for Use *(Describe)*
The IBS Implant System II is intended to replace missing teeth to restore chewing function. The IBS Implant System II 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.

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

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Device Information

- Trade Name: IBS Implant System II
- 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: 02/14/2017

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 II is consists of dental fixtures, screws and multiunit abutment cylinders.
The diameters and lengths of the IBS Implant System II are below:

1) Fixture: NR Fix

Diameter	Length
Ø3.5mm	9 mm
	11 mm
	13 mm
Ø3.8 mm	7 mm
	10 mm
	11 mm
	12 mm
	13 mm
	14 mm
	15 mm

2) Fixture: Magic FC

Diameter	Length
Ø4.0 mm	7 mm
	9 mm
	11 mm
	13 mm
	15 mm
Ø4.5 mm	7 mm
	9 mm
	11 mm
	13 mm
	15 mm
Ø5.0mm	7 mm
	9 mm
	11 mm
	13 mm
	15 mm
Ø5.5 mm	7 mm
	9 mm
	11 mm
	13 mm
	15 mm
Ø6.0 mm	7 mm
	9 mm
	11 mm
	13 mm
	15 mm
Ø6.5 mm	7 mm
	9 mm
	11 mm
	13 mm
	15 mm

The implant-abutment connection is tight and precise fitting with internal hex and Morse taper bevel.
The subject device is compatible with the following abutments:

K number	Compatible Abutments
K153350	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

The surface of the system has been treated with SLA (sand-blasted, large-grit, acid-etched) by increasing the area of bone-implant interface.
Fixtures and cover screw are packaged together and supplied sterile.
Cover Screw (HISC00) was cleared from K140806.

Cylinders are used in conjunction with screw retained type Abutment to provide support for screw type final prosthesis, and for fabrication of custom abutment for screw retained restorations.

The screw retained type is used for fabricating the single-unit prosthesis, and the multi-unit prosthesis.

3) Multiunit Ti Cylinder

Diameter	Length	Remark
Ø3.5 mm	12 mm	Hexa/Non-Hexa
Ø4.0 mm		
Ø4.5 mm		
Ø5.0 mm		
Ø5.5 mm		
Ø6.0 mm		

4) Multiunit Temporary Cylinder

Diameter	Length	Remark
Ø3.5 mm	12 mm	Hexa/Non-Hexa
Ø4.0 mm		
Ø4.5 mm		
Ø5.0 mm		
Ø5.5 mm		
Ø6.0 mm		

5) Multiunit Plastic Cylinder

Diameter	Length	Remark
Ø3.5 mm	12 mm	Hexa/Non-Hexa
Ø4.0 mm		
Ø4.5 mm		
Ø5.0 mm		
Ø5.5 mm		
Ø6.0 mm		

6) Magic Motion

Magic Motion is an attachment-retained prosthetic product, which is used with patients with a fully edentulous maxilla. It is an one-piece structure. Various collar heights of the magic motions can be selected based on the gingival height. Magic motion does not have movement and it is a solid type.

Product name	Diameter	Cuff	Length
Magic Motion	3.9 mm	1 mm	9.65 mm
		2 mm	10.65 mm
		3 mm	11.65 mm
		4 mm	12.65 mm
		5 mm	13.65 mm
		6 mm	14.65 mm
		7 mm	15.65 mm
		8 mm	16.65 mm

Indication for Use

The IBS Implant System II is intended to replace missing teeth to restore chewing function. The IBS Implant System II 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 from Ti 6AL 4V Eli (Conforming to ASTM Standard F-136). The abutments are fabricated from Ti 6AL 4V Eli and Poly Diacetate.

Non-Clinical Data:

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Biocompatibility tests according to ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-11
- Endotoxin Test according to USP <85>

Below tests were performed for predicate devices and leveraged for the subject device:

- Gamma Sterilization Validation Test according to ISO11137-1,- 2 referenced in K153350
- End User Steam Sterilization Test according to AAMI TIR12:2010 referenced in K140806
- Shelf life Validation Test according to ISO 11607-1, -2, and ASTM F1980-07 referenced in K153350
- Fatigue Test according to ISO 14801 referenced in K153350

Non-clinical tests followed the recommendations in the "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant abutments". Surface treatment analysis were performed to support the decision of substantial equivalence.

Comparison to Predicate Devices:

1) Fixtures

- K153350, IBS Implant System by InnoBioSurg Co., Ltd.
- K140440, Noris Medical Dental Implants System by Noris Medical Ltd.

	Subject device	Primary Predicate device	Reference Device
Product Name	IBS Implant System Ⅱ	IBS Implant System	Noris Medical Dental Implants System
510(k) Product code Class	N/A DZE II	K153350 DZE II	K140440 DZE II
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.	Noris Medical Ltd.
Indication for use	Identical to the Predicate devices	Intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement-retained,	Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic

		screw- retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading.	devices that may aid in restoring the patients chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Design			
Composition of Material	Titanium Alloy Ti-6Al-4V Eli ASTM F136	Titanium Alloy Ti-6Al-4V Eli ASTM F136	Titanium Alloy Ti-6Al-4V Eli ASTM F136
Prosthetic connection	Identical	Internal Hex	Internal Hex
Endosseous Implant	Identical	Tapered, macro threads	Tapered, micro · macro threads
Components	Identical	Various abutments and accessories	Various abutments and accessories
Range of Diameters (mm)	Identical	NR Fix : 3.5, 3.8mm Magic Fc : 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 mm	3.3, 3.75, 4.2, 5, 6mm
Range of Lengths (mm)	Identical	NR Fix : 9, 10, 11, 12, 13, 14mm Magic FC : 7, 9, 11, 13, 15mm	8, 10, 11.5, 13, 16mm
Modified Surface	S.L.A	R.B.M.	S.L.A
Surgical Technique	Identical	1 stage and 2 stage, self tapping	1 stage and 2 stage, self tapping
Gamma Sterilization	Identical	Yes	Yes

2) Abutment

- K153350, IBS Implant System by InnoBioSurg Co., Ltd.
- K142813, Biogenesis Implant System-Kisses by Biogenesis Co., Ltd.

	Subject Device	**Primary Predicate**	**Reference Predicate**	**Reference Predicate**
Manufacturer	Innobiosurg Co., Ltd	Innobiosurg Co., Ltd	Biogenesis Co., Ltd	Innobiosurg Co., Ltd
Device Name	IBS Implant System II	IBS Implant System	Biogensis Implant System-Kisses	IBS Implant System
510(k) No.	N/A	K153350	K142813	K140806
Design	 Cylinders	 Burn out (Plastic)Cylinder	-	-
	 Magic Motion	-		-
Indication for use	Identical to the Predicate devices	IBS Implant system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The Biogenesis Implant System – Kisses is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations and terminal or intermediate abutment support for fixed bridgework. The Biogenesis Implant System – Kisses is for single and two stage surgical procedures. It is	IBS Implant system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

			for delayed loading.	
Connection Type	Internal Hex-Connected	Internal Hex-Connected	-	Internal Hex-Connected
Diameters	Cylinders : 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 mm Magic Motion : 3.9 mm	4.5, 5.5, 6.5mm	3.0mm, 3.5mm	4.0, 4.5, 5.0, 5.5, 6.0, 6.5mm
Lengths	Cylinders : 12mm	14.8mm	-	10.6, 11.6, 12.6, 13.6, 14.6, 15.6mm
G/H Length (mm)	Magic Motion :1mm-8mm	1mm-4mm	0.5mm-7mm	1mm-4mm
Angle(°)	No Angulation	No Angulation	No Angulation	No Angulation
Material	Titanium Alloy Poly Diacetate	Titanium Alloy Poly Diacetate	Titanium Alloy	Titanium Alloy
Surface	Machine	Machine	Anodizing coloring – Gold color (Entire Body)	Machine
Sterilization	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile

Substantial Equivalence Discussion

Similarities

The indications for use, material, general shape design, dimension, surface, connection to abutment method, application method and sterilization method between the IBS Implant System II and the predicate devices are similar.

Differences

1) Fixtures

The difference between the subject device and the primary predicate device is the surface treatment method of the fixture. The surface of the fixture of the primary predicate has been treated with RBM (Resorbable Blasted media) and the surface of the fixture of the subject device has been treated with SLA (sand-blasted, large-grit, acid-etched). The reference predicate device, Noris Medical Dental Implants System (K140440) has the same surface treatment as the subject device.

2) Cylinders

Another difference is the dimension and design of the multiunit abutment cylinder. The range of the diameters of the subject device is 3.5 to 6.0mm and the length of the subject device is 12mm. The range of the diameters of the primary predicate device is 4.5 to 6.5mm and the length of the primary predicate device is 14.8mm. While the outer surface of the predicate device is smooth, the outer surface of the subject device is designed with grooves, which allow resin to stick well and thus make it easier to manufacture the frame of the teeth.

3) Magic Motions

The difference is the diameter size of the magic motion. The diameter of the subject device is 3.9mm and is a bit bigger than the predicate's which are 3.0 mm and 3.5mm.

Brief Discussion

The differences between the subject device and predicate device are the fixture's surface treatment, cylinders' design and dimension, and magic motions' diameter size. For the fixture's surface treatment, as we provided the SLA analysis information and the predicate, K140440 has the same surface treatment.
According to the indication for use of the cylinder, a cylinder with appropriate diameter and length is used for hand-milling. Since the selection of an appropriate cylinder may reduce the milling time and deletion, the smaller diameter or the shorter length in comparison with the predicate device does not affect the substantial equivalence. An appropriate size of cylinder locked on the abutment may be used.
Accordingly we can claim the substantially equivalence of the subject device to predicate device.
For the magic motion's size, as the subject device's diameter is bigger than the predicate's.
Any differences between the IBS Implant System II and predicate device do not raise questions.
Accordingly we can claim the substantially equivalence of the IBS Implant System II to predicate device.

Conclusion

The IBS Implant System II, 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 II and its predicates are substantially equivalent.