



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 25, 2016

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

Re: K152520
Trade/Device Name: Magicore System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 16, 2015
Received: December 22, 2015

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,



Tina Kiang -S

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

Indications for Use

510(k) Number (if known)
K152520

Device Name
Magicore System

Indications for Use (Describe)

The Magicore System is intended to replace missing teeth to restore chewing function. The Magicore 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter

InnoBioSurg Co., Ltd.
 Bo-reumYoo
 44-19, Techno 10-ro, Yuseong-gu,
 Daejeon, 305-510
 Republic of Korea
 Email: bryoo@ibsimplant.com
 Tel.+82-42-933-2879
 Fax.+82-42-933-2881

Official Correspondent

WithUS Group Inc
 April Lee
 2531 Pepperdale Drive
 Rowland Heights, CA 91748
 USA
 Email:withus6664@gmail.com
 Phone: 1-909-274-9971
 Fax: 1-909-460-8122

Device Information

- Trade Name: Magicore 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: 1/22/2016

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 Magicore 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).

The Fixture diameters are 4, 4.5, 5, 5.5, 6, 6.5mm and lengths are 7, 9, 11, 13mm in this system.

The contained various abutments and accessories in the system are abutment screw, magicore abutment &cap, healing cap (color anodizing: yellow, blue, green, and purple). The abutments are provided straight only and that they are no intended to be modified to provide an angle correction.

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.

Indication for Use

The Magicore System is intended to replace missing teeth to restore chewing function. The Magicore 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.

Materials:

The dental implants are fabricated from Ti 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 11137-2:2006 and surface treatment analysis were used to support the decision of substantial equivalence.

A biocompatibility evaluation was conducted and since all the materials were used in the company’s own predicate or conform to an FDA consensus standard, no additional biocompatibility testing was deemed necessary.

Shelf-life validation was conducted on the packaging of the sterile device according to ASTM 1980 to validate the 5 year shelf life via real-time aging.

Predicate Device:

1) Comparison to Predicate Devices: (implant)

- K073247, US/SS/GS SYSTEM manufactured by OSSETEM Implant Co., Ltd.
- (Reference Device) K140806, IBS Implant System manufactured by Innobiosurg Co., Ltd.

	Subject device	Predicate device	Reference device
Product Name	MagiCore System	US/SS/GS SYSTEM	IBS Implant System
510(k) Product code Class	K152520 DZE,NHA II	K073247 DZE II	K140806 DZE/NHA II
Manufacturer	InnoBioSurg Co., Ltd.	OSSETEM Co., Ltd.	InnoBioSurg Co., Ltd.
Indication for use	The MagiCore System is intended to replace missing teeth to restore chewing function. The MagiCore can be placed in support of single or multiple-unit restorations including;	Intended for use in partially or fully edentulous mandible and maxillae, in support of single or multiple-unit restorations including; cement-retained, screw-retained, overdenture restorations,	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

	<p>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.</p>	<p>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.</p>	<p>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.</p>
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
Neck Length	1,2,3mm	1.8mm, 2.8mm	-
Fixture Type	NON Submerged	NON Submerged	Submerged
Endosseous Implant	Tapered, macro threads	Tapered, Macro threads	Tapered, macro and micro threads
Components	Various abutments and accessories	Various abutments and accessories	Various abutments and accessories
Range of Diameters (mm)	4, 4.5, 5, 5.5, 6, 6.5mm	4.0 – 6.0mm	3.8, 4.3, 4.8, 5.3, 5.8,6.3 mm
Range of Lengths(mm)	7 mm – 13 mm	7 mm – 13 mm	7 mm – 15 mm
Modified Surface	R.B.M.	R.B.M.	R.B.M.
Surgical Technique	1 stage and 2 stage, self tapping	1 stage and 2 stage, self tapping	1 stage and 2 stage, self tapping
Gamma Sterilization	Yes	Yes	Yes
Body Contact	Direct	Direct	Direct
Contact Duration	Class C (>30days)	Class C (>30days)	Class C (>30days)

2) Comparison chart for abutments

	Subject device	Predicate device	Reference device
Product Name	MagiCore System	US/SS/GS SYSTEM	IBS Implant System
510(k) Product code Class	K152520 DZE/NHA II	K073247 DZE II	K140806 DZE/NHA II
Manufacturer	InnoBioSurg Co., Ltd.	OSSETEM Co., Ltd.	InnoBioSurg Co., Ltd.
Indication for use	<p>The MagiCore System is intended to replace missing teeth to restore chewing function. The MagiCore 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.</p>	<p>Intended 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. This system is dedicated</p> <p>For one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading.</p>	<p>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.</p>
Abutment design			
Diameter	3.5, 3.86, 4.3, 4.6mm		4.0, 4.5, 5.0, 5.5, 6.0, 6.5mm
length	9.6, 10.6, 11.6mm		10.6, 11.6, 12.6, 13.6, 14.6, 15.6mm

Healing cap Design			
Diameter	5.5mm		4.0, 4.5, 5.0, 5.5, 6.0mm
length	7.3mm		9.1, 10.1, 11.1, 12.1, 13.1, 14.1mm
Abutment cap design			
diameter	5.5, 6.0, 6.5, 7.0mm		4.5, 5.0, 5.5, 6.0, 6.5, 7.0mm
length	5.5, 6.5, 7.5, 8.5, 9.5mm		5.1, 6.6, 8.1mm
Closing screw design			
diameter	3.5mm		3.4mm
length	5.65mm		5.65mm
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
Materials of Magicore Abutment Cap	PolyDiacetate	Polycarbonate polymer	PolyDiacetate
Contact Duration	Class C (>30days)	Class C (>30days)	Class C (>30days)

Substantial Equivalence Discussion

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

The differences between them are the external shape of the fixture and fixture diameters.

The subject device and primary predicate have slightly different Indications for Use language. However, the difference in language does not change the intended use or substantial equivalence.

Any differences between the Magicore System and predicate device do not raise new types of safety or effectiveness issues. Accordingly we can claim the substantially equivalence of the Magicore System to predicate device.

Conclusion

The Magicore 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, Magicore System and its predicates are substantially equivalent.