July 15, 2020

InnoBioSurg Co., Ltd.
% April Lee
Consultant
Withus Group Inc.
106 Superior
Irvine, California 92620

Re: K201621
Trade/Device Name: Magicore II System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 13, 2020
Received: June 15, 2020

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201621

Device Name
Magicore II System

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

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

- K number: K201621
- Trade Name: Magicore II System
- Common Name: Endosseous dental implant abutment
- Classification Name: Endosseous dental implant abutment
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date prepared: 07/10/2020

Predicate Devices:
The subject device is substantially equivalent to the following predicate devices:

Primary Predicate
K192197, Magicore II System manufactured by InnoBioSurg Co., Ltd.

Indication for Use
The Magicore II System is intended to replace missing teeth to restore chewing function. The Magicore II 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.

Device Description
This submission is to add new abutments to the previously cleared device, Magicore II System (K192197).
The newly added abutments are Magic Multiunit Abutments (Screw type – Hex, Non-Hex, Cemented type – Hex, Non-Hex) with the new angulations of 5, 10, 20°

For Magic Multiunit Cylinder, Magic Multiunit Abutment ST, and Magic Multi Abutment Cap, no other changes are being made to the previous clearances except for model names.

The Abutments are fabricated from Ti-6AL-4V Eli (Conforming to ASTM Standard F-136).

The dimension ranges of the abutments are below:

Abutments	Diameters (Ø)	Lengths (mm)	Angulation (˚)
Magic Multiunit Abutment (Screw type – Hex, Non-Hex, Cemented type – Hex, Non-Hex) (Cleared in K192197)	4.8	3.9- 7.5	5 (Newly Added)
		4.2-7.8	10 (Newly Added)
		4.8-8.4	20 (Newly Added)
	5.8	4-7.6	5 (Newly Added)
		4.3-7.9	10 (Newly Added)
		4.9- 8.5	20 (Newly Added)

The subject abutments are compatible with implants in K192197.
The Abutments are provided non-sterile and packaged separately. The abutment should be sterilized before use.

The purpose of this submission is

- To add a new Magic Multiunit Abutment with angle 5, 10, 20°.
- To change the product name

Product Name in K192197	Product Name in Subject system
Magic Multi Abutment	Magic Multiunit Abutment
Magic Multi Cylinder	Magic Multiunit Cylinder
Magic Multi Abutment ST	Magic Multiunit Abutment ST
Healing Cap	Magic Multiunit Abutment Cap

- To change the screw quantity 1ea to 2ea in a set package

Summaries of Technology Characteristics:

<Magic Multiunit Abutment>

	Subject Device	**Primary Predicate**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore II System	Magicore II System
Abutment Name	Magic Multiunit Abutment	Magic Multi Abutment
510(k) No.	NA	K192197
Instructions for Use	The Magicore II System is intended to replace missing teeth to restore chewing function. The Magicore II 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 Magicore II System is intended to replace missing teeth to restore chewing function. The Magicore II 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.
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (Ø)	4.8, 5.8	4.8, 5.8
Gingiva Height (mm)	1.5, 2.5, 3.5, 4.5	1.5, 2.5, 3.5, 4.5
Angulation (°)	5, 10, 20°	15, 25°
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization

Similarities

Magic Multiunit Abutments with 5, 10, 20° angulations have the same fundamental scientific technology, principle of operation, design, technology, functions, dimensions and materials.

Differences

- New Magic Multiunit Abutment: The Abutments with 5 °, 10 °, 20 ° angulation are added to the new subject system. Since the primary predicate's abutment is worst case (largest angulation), the difference doesn't impact product's safety and effectiveness and it demonstrates substantial equivalence.

Non-Clinical Data

No need to perform any non-clinical testing for the subject device since the subject device and predicate device are substantially equivalent in indications, fundamental technology, material and design.
Although the dimensions and angulations are different, by performing product's dimensional comparison analysis, it concluded that the predicate device is the mechanical worst case and demonstrated the substantial equivalence.
As both subject device and predicate device has same material and manufacturing process, it demonstrates the subject device is biocompatible and substantially equivalent.
The end user sterilization performed in predicate device can be leveraged for the subject device because both products have same material, manufacturing process, and sterility process and it demonstrated the substantial equivalence. The change of the screw quantity from 1 each to 2 each does not affect the sterility process.

Conclusion

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