June 9, 2020

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

Re: K200753
Trade/Device Name: IBS Implant System II
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 8, 2020
Received: May 13, 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)*
K200753

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.

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

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510(k) Summary

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Device Information

- Trade Name: IBS Implant System II
- 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: 06/09/2020

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

Primary Predicate
K162099, IBS Implant System II manufactured by InnoBioSurg Co., Ltd.

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.

Device Description
This submission is to add new magic Motion Abutment to the previously cleared device, IBS Implant System II (K162099).
The Magic Motion Abutment system is composed of Magic Motion Abutment, Housing and O-ring. The Magic Motion Abutment is a device made of a material such as Ti-6AL-4V Eli (Conforming to ASTM Standard F-136). Magic Motion is an attachment-retained prosthetic product, which is used with patients with a fully edentulous maxilla. It is a 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.

The diameters and lengths of the Magic Motion Abutment are below:

Magic Motion

Product name	Diameter (Ø)	Cuff (mm)	Length (mm)
Magic Motion	3.9 (Cleared in K162099 – Changed product codes)	1	9.65
		2	10.65
		3	11.65
		4	12.65
		5	13.65
		6	14.65
		7	15.65
		8	16.65
	4 (Newly Added)	1.4	10.05
		2.4	11.05
		3.4	12.05
		4.4	13.05
		5.4	14.05
		6.4	15.05
		7.4	16.05

The subject device is compatible with the following Implants:

K number	Compatible Implants
K162099	IBS Implant System II

The Magic Motion Abutment is provided non-sterile and packaged separately. The abutment should be sterilized before use. The purpose of this submission is to change the product codes for the current cleared magic motion abutments add the new Magic Motion Abutments.

Materials

The Magic Motion Abutment and Housing are fabricated from Ti-6AL-4V Eli. The Magic Motion O-ring is fabricated from silicon rubber.

Summaries of Technology Characteristics:

K162099, IBS Implant System II by InnoBioSurg Co., Ltd.

	Subject Device	**Primary Predicate**
Manufacturer	Innobiosurg Co., Ltd	Innobiosurg Co., Ltd
Device Name	Magic Motion Abutment	IBS Implant System II
510(k) No.	K200753	K162099
Indications 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.	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.
Design		
Connection Type	Internal Hex-Connected	Internal Hex-Connected
Hex	3.6	3.47
Diameters (Ø)	4.0 mm	3.9 mm
Lengths	10.05-16.05 mm	9.65-16.65 mm
G/H Length (mm)	1.4-7.4 mm	1-8 mm
Angle (°)	No Angulation	No Angulation
Material	Titanium Alloy (ASTM F 136)	Titanium Alloy (ASTM F 136)
Surface	Machine	Machine
Sterilization	End User Sterilization	End User Sterilization
Diameters and Heights of Magic Motion Housing	Diameter: 5.3 (Ø) Heights: 3.0 mm	Diameter: 5.0 (Ø) Heights: 3.0 mm

Similarities

The subject Magic Motion Abutment has a substantially equivalent intended use as the identified predicates. The subject device is similar in fundamental scientific technology, principle of operation, design, technology, functions, dimensions and materials.

Differences

- New Magic Motion Abutment: Compared to the primary predicate device, the subject device's diameter and hex of subject device is larger. In addition, the neck and head diameter of the subject magic motion abutment is a bit larger than the predicate. Because of the larger neck and head diameter, the design of the

head shape of the subject magic motion abutment is changed to more round. This difference is to improve the connection of Magic Motion and Magic Motion Housing and doesn't impact product's substantial equivalence.
- New Magic Motion Housing: The height and diameter of subject device is larger than primary predicate device, however, it doesn't impact product's substantial equivalence.

Non-Clinical Data

Design Control Activity Summary was provided including dimensional comparison analysis with respective acceptance criteria to demonstrate that the subject device is substantially equivalent with the predicate device.

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

- End User Steam Sterilization Test according to AAMI TIR12:2010 referenced in K140806
- Biocompatibility tests according to ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-11 referenced in K162099

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device. Non-clinical tests followed the recommendations in the "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant abutments".

Conclusion

The subject Magic Motion Abutment constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This abutment has the same intended use and fundamental scientific technology as its predicate device. Therefore, Magic Motion Abutment and its predicate are substantially equivalent.