August 27, 2020

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

Re: K201981
Trade/Device Name: Magicore System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 14, 2020
Received: August 19, 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)*
K201981

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.

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510(k) Summary

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Device Information

- Trade Name: Magicore System
- Common Name: Endosseous dental implant abutment
- Classification Name: Endosseous dental implant abutment
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date prepared: 08/26/2020

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

Primary Predicate
K152520, Magicore System manufactured by InnoBioSurg Co., Ltd.

Reference Device
K140806, IBS Implant System by InnoBioSurg Co., Ltd.
K162099, IBS Implant System II by InnoBioSurg Co., Ltd.
K192197, Magicore II System manufactured by InnoBioSurg Co., Ltd.
K181138, IS-III active System manufactured by Neobiotech Co., Ltd.
K171027, Dentis Dental Implant System manufactured by Dentis Co., Ltd.

General Description

This submission is to add new implants and abutments to the previously cleared device, Magicore System (K152520).
The newly added implants and abutments are below:
Fixture

- Magicore (4mm of Neck length Implants)
- Magicore (Cutting Edge)

Abutment

- Magicore Solid Abutment
- Healing Cap

For Magicore Solid Abutment Cap, no other changes are being made to the previous clearance except for product name change.

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 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 dimension ranges of the fixtures are below:

Fixture	Diameters (Ø)	Neck Lengths (mm)	Length (mm)
Magicore (Cleared in K152520)	4	1, 2, 3	7, 8, 9, 10, 11, 12, 13
		4 (Newly Added)	
	4.5	1, 2, 3	7, 8, 9, 10, 11, 12, 13
		4 (Newly Added)	
	5	1, 2, 3	7, 8, 9, 10, 11, 12, 13
		4 (Newly Added)	
	5.5	1, 2, 3	7, 8, 9, 10, 11, 12, 13
		4 (Newly Added)	
	6	1, 2, 3	7, 8, 9, 10, 11, 12, 13
		4 (Newly Added)	
	6.5	1, 2, 3	7, 8, 9, 10, 11, 12, 13
		4 (Newly Added)	
Fixture	**Diameters (Ø)**	**Neck Lengths (mm)**	**Length (mm)**
Magicore (Cutting Edge) (Newly Added)	4	1,2,3,4	7, 8, 9, 10, 11, 12, 13
	4.5	1,2,3,4	7, 8, 9, 10, 11, 12, 13
	5	1,2,3,4	7, 8, 9, 10, 11, 12, 13
	5.5	1,2,3,4	7, 8, 9, 10, 11, 12, 13
	6	1,2,3,4	7, 8, 9, 10, 11, 12, 13
	6.5	1,2,3,4	7, 8, 9, 10, 11, 12, 13

Below is abutments dimension range:

Abutments	Diameters (Ø)	Length of Cuff (mm)
Magicore Solid Abutment (Cleared in K152520)	3.5, 3.86, 4.3, 4.6	7.6 (Newly Added)
		8.6 (Newly Added)
		9.6, 10.6, 11.6
Magicore Solid Abutment Cap (Cleared in K152520)	5.5, 6.0, 6.5, 7.0	5.5, 6.5, 7.5, 8.5, 9.5
Healing Cap (Cleared in K152520)	5.3 (Newly Added)	Cuff: 2.8, 5.3 (Newly Added)
	5.5, 6.0	Cuff: 4.2
	6.3 (Newly Added)	Cuff: 2.8, 5.3 (Newly Added)
	6.5, 6.9, 7.6	Cuff: 4.2

Tolerance of dimension for Fixtures and Abutments shall be within ±1% range.
Fixtures and abutments are packaged separately. The Fixtures are supplied sterile. Fixtures are packaged with closing screw.
The Healing cap, Magicore Solid Abutment and Magicore Solid Abutment Caps are provided non-sterile and packaged together. The Healing Cap, Magicore Solid Abutments and Magicore Solid Abutment Caps should be sterilized before use.

The purpose of this submission is

- To add new Magicore Fixtures with neck length 4mm.
- To change the product code of the previously cleared Magicore Fixtures by changing “C” to “B” at the end of the product code.
- To add new Magicore Fixtures (Cutting Edge).
- To add new Healing Caps, 5.3, 6.3mm diameters with 2.8, 5.3mm cuff lengths.
- To add new Magicore Solid Abutments, 3.5, 3.86, 4.3, 4.6mm diameters with 7.6, 8.6mm lengths
- To change the product name as below:

Product Name in K192197	New Product Name in Subject system
Magicore Abutment	Magicore **Solid** Abutment
Magicore Abutment Cap	Magicore **Solid** Abutment Cap

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. This system is intended for delayed loading.

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

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Summaries of Technology Characteristics:

1) Fixture

	Subject Device	Primary Predicate	Reference Device
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd
Device Name	Magicore System	Magicore System	Magicore II System
510(k) No.	N/A	K152520	K192197
Indications for use	The Magicore System is intended to replace missing teeth to restore chewing function. The Magicore 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 System is intended to replace missing teeth to restore chewing function. The Magicore 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.
Design			
	Cutting Edge, Non-Cutting Edge	Non-Cutting Edge	Cutting Edge, Non-Cutting Edge
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

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Connection	Internal Hex Non - Submerged	Internal Hex Non - Submerged	Internal Hex Non - Submerged
Endosseous Implant	Tapered, macro threads	Tapered, macro threads	Tapered, macro threads
Range of Diameters (mm)	4.0, 4.5, 5.0, 5.5, 6.0, 6.5mm	4.0, 4.5, 5.0, 5.5, 6.0, 6.5mm	4.0, 4.5, 5, 5.5, 6, 6.5mm
Neck Length (mm)	1, 2, 3, 4mm	1, 2, 3mm	1, 2, 3, 4mm
Range of Lengths (mm)	7, 8, 9, 10, 11, 12, 13mm	7, 8, 9, 10, 11, 12, 13mm	7, 8, 9, 10, 11, 12, 13mm
Modified Surface	R.B.M	R.B.M	S.L.A
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

Similarities
The Magicore System has same device characteristics with the Primary predicate and Reference devices such as diameters, Length, intended use, material, functions, general shape (Design), structure and applied production method.

Differences
New Magicore Fixture with 4mm neck length: Compared to the Primary predicate, the subject's device's neck length is longer, however, the neck length of subject device is included in range of reference predicate neck length, Magicore II System. Therefore, it doesn't impact product's substantial equivalence.

2) Abutments

<Healing Cap>

	Subject Device	Primary Predicate	Reference Device
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd	Neobiotech Co., Ltd.
Device Name	Magicore System	Magicore System	IS-III active System
510(k) No.	N/A	K152520	K181138
Composition of Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Design			
Range of Diameters (mm)	5.3, 5.5, 6.0, 6.3, 6.5, 6.9, 7.6mm	5.5, 6.0, 6.5, 6.9, 7.6mm	4.0, 4.5, 4.8, 5.5, 6.0, 6.8, 8.0, 9.0mm
Cuff (mm)	2.8, 4.2, 5.3mm	4.2mm	2.3, 2.8, 3.3, 3.8, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.8mm
Surface treatment	Anodizing (Green, Purple, Blue, Yellow)	Anodizing (Green, Purple, Blue, Yellow)	Machine
Gamma Sterilization	No	No	Yes

Similarities
The Healing Cap has substantially equivalent in intended use, fundamental scientific technology, principle of operation, design, functions, surface treatment and materials as the identified predicates.

Differences
Dimensions: Compared to the Primary predicate device 5.3, 6.3mm diameter with 2.8mm 5.3mm cuff lengths are added to the new subject system. The smaller diameters and shorter cuffs of the subject device allows space when healing gingiva. To support the dimensional differences, we selected K181138 as the reference device, which covers the subject device's dimensional range. Therefore, the difference doesn't affect product's fundamental functions.

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<Magicore Solid Abutment>

	Subject Device	Primary Predicate	Reference Predicate
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd
Device Name	Magicore System	Magicore System	Magicore System II
Model Name	Magicore Solid Abutment	Magicore Abutment	Short Abutment
510(k) No.	N/A	K152520	K192197
Composition of Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Design			
Range of Diameters (mm)	3.5, 3.86, 4.3, 4.6mm	3.5, 3.86, 4.3, 4.6mm	3.5, 3.86, 4.3, 4.6mm
Range of Height (mm)	2, 3, 4, 5, 6mm	4, 5, 6mm	2, 3, 4, 5, 6mm
Surface Treatment	N/A	N/A	N/A
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization

Similarities
The Magicore Solid Abutment has a substantially equivalent intended use as the identified predicates. The subject device is same in fundamental scientific technology, manufacture, principle of operation, general shape (design), functions diameter and material.

Differences
New Magicore Solid Abutment: Compared to the dimension of Primary predicate and Subject device is same. The difference between the subject device and predicate device (K192197) is integral with screw. The difference doesn't affect product's fundamental functions.

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<Magicore Solid Abutment Cap>

	Subject Device	Primary Predicate
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd
Device Name	Magicore System	Magicore System
Model Name	Magicore Solid Abutment Cap	Magicore Abutment Cap
510(k) No.	N/A	K152520
Design		
Composition of Material	Poly Oxy Methylene (POM)	Poly Oxy Methylene (POM)
Range of Diameters (mm)	5.5, 6.0, 6.5, 7.0mm	5.5, 6.0, 6.5, 7.0mm
Range of Lengths (mm)	5.5, 6.5, 7.5, 8.5, 9.5mm	5.5, 6.5, 7.5, 8.5, 9.5mm
Sterilization	End Use Sterilization	End Use Sterilization

Similarities
The Magicore Solid Abutment Cap has same fundamental scientific technology, principle of operation, general shape (design), functions, diameter and material to the predicate.

Differences
Only change the product name. Therefore, it doesn't impact product's substantial equivalence.

Non-Clinical Data:

No need to perform any new additional non-clinical testing for the subject device since the subject device compared to predicate device and reference devices are substantially equivalent in indications, fundamental technology, material and design. The predicate and reference devices may be leveraged for the subject devices because of using the same materials, manufacturing methods, and sterilization procedures. Although the dimensions are slightly different, it doesn't impact the ability to determine substantial equivalence of the subject devices because the predicate and reference devices are the worst case based on the product's dimensional comparison analysis provided.

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

- Sterilization validation according to ISO 11137-1 and ISO 11137-2 on Fixtures referenced in K140806
- Bacterial endotoxin Testing according to USP <85> on Fixtures as referenced in K162099
- Shelf Life Test according to ASTM F1980 on fixtures referenced in K152520
- Biocompatibility testing according to ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2007, ISO 10993-10:2010 and ISO 10993-11:2006 on fixtures referenced in K140806 and K152520
- Biocompatibility testing according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-6:2007, and ISO 10993-10:2010 on abutments referenced in K152520
- End User Sterilization Validation testing according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1 on Abutments referenced in K192197

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.
The surface modification information with RBM (Resorbable Blasted media) was provided. To compare surface modification between the subject and predicate devices, K152520, surface roughness, surface composition analysis, and SEM imaging were provided and it demonstrate the substantial equivalence.
The fatigue testing per ISO 14801 was not conducted as the subject device does not contain any angulated abutments.
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 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.