October 15, 2021

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

Re: K212517
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: September 10, 2021
Received: September 17, 2021

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 Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212517

Device Name
Magicore System

Indications for Use *(Describe)*
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.

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

Submitter
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Device Information

- Trade Name: Magicore System
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3640
- Date prepared: 10/14/2021

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

Primary Predicate
K201981, Magicore System manufactured by InnoBioSurg Co., Ltd.

Reference Device
K153639, OneQ-SL s-Clean Implant System manufactured by Dentis Co., Ltd.
K192197, Magicore II System manufactured by InnoBioSurg Co., Ltd.
K201621, Magicore II System manufactured by InnoBioSurg Co., Ltd.
K202418, Magic UCLA Abutment System manufactured by InnoBioSurg Co., Ltd.

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.

Device Description

This submission is to add new fixtures and abutments to the previously cleared device, Magicore System (K201981), Magicore II System (K201621), Magicore II System (K192197), and Magic UCLA Abutment System (K202418).

The fixtures and abutments in this system are below:

1) Fixture

- Magicore
- Magicore (Cutting Edge)

2) Abutment

- Magic Multiunit Abutment (Screw type – Hex, Non-Hex & Cemented type – Hex, Non-Hex)
- Magic Multiunit UCLA Cylinder
- Magic Multiunit Cap
- Magic Abutment (Screw type – Hex, Non-Hex & Cemented type – Hex, Non-Hex)
- Magic UCLA Cement Retained Type (Hex, Non-Hex)
- Magic Cylinder (Hex, Non-Hex, Post)
- Magic Multiunit Cylinder (Hex, Non-Hex, Post)
- Magicore Healing Cap
- Magicore Healing Cap Screw
- Cylinder Screw

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, cylinders, caps 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 Magicore implant is treated with RBM (Resorbable Blasted media).

Below is the fixture dimension range:

<table>
<tr><th>Fixture</th><th>Platform Diameters (Ø)</th><th>Fixture Diameters (Ø)</th><th>Cuff Lengths (mm)</th><th>Implantable Lengths (mm)</th></tr>
<tr><td rowspan="4">Magicore (Cleared in K201981)</td><td rowspan="2">5.2</td><td>4.0, 4.5</td><td rowspan="8">1. 2, 3, 4</td><td rowspan="8">7, 8, 9, 10, 11, 12, 13</td></tr>
<tr><td>5.0, 5.5, 6.0, 6.5 (Newly Added)</td></tr>
<tr><td rowspan="2">5.7</td><td>4.5, 5.0, 5.5, 6.0, 6.5</td></tr>
<tr><td>7.0, 7.5, 7.8 (Newly Added)</td></tr>
<tr><td rowspan="4">Magicore, Cutting Edge type (Cleared in K201981)</td><td rowspan="2">5.2</td><td>4.0, 4.5</td></tr>
<tr><td>5.0, 5.5, 6.0, 6.5 (Newly Added)</td></tr>
<tr><td rowspan="2">5.7</td><td>4.5, 5.0, 5.5, 6.0, 6.5</td></tr>
<tr><td>7.0, 7.5, 7.8 (Newly Added)</td></tr>
</table>

Fixture (Subject Device)	Platform Diameter (Ø)	Fixture Diameters (Ø)	Cuff Lengths (mm)	Implantable Lengths (mm)
Magicore	5.2	5.0, 5.5, 6.0, 6.5	1, 2, 3, 4	7, 8, 9, 10, 11, 12, 13
	5.7	7.0		7, 8, 9, 10
		7.5		7, 8, 9
		7.8		7, 8
Magicore (Cutting Edge type)	5.2	5.0, 5.5, 6.0, 6.5		7, 8, 9, 10, 11, 12, 13
	5.7	7.0		7, 8, 9, 10
		7.5		7, 8, 9
		7.8		7, 8

The subject fixtures are provided sterile.
The subject fixtures are compatible with the abutment in this submission and the abutments of K192197, K201621, K201981 and K202418.
Below is the abutment dimension range:

Abutments	Diameters (Ø)	Length (mm)	Angulation (°)
Magic Multiunit Abutment (Screw type – Hex, Non-Hex, Cemented type – Hex, Non-Hex) (Cleared in K201621)	4.8, 5.8	1.5, 2.5, 3.5, 4.5	5, 10, 15, 20, 25
		2.3 (Length Change)	0 (Newly Added)
Magic Multiunit UCLA Cylinder (Cleared in K202418)	4.5, 5.0, 5.2, 6.0, 6.2, 6.3	8.5, 8.75, 8.9, 10.2, 10.4, 10.5	-
	5.4, 6.4 (Newly Added)	11.2 (Newly Added)	
Magic Cylinder (Cleared in K201621)	5.0, 6.0	10	-
		10.6 (Length Change)	
Magic Multiunit Cylinder (Cleared in K201621)	5.0, 6.0	10	-
	5.4, 6.4 (Newly Added)		
Magic Multiunit Cap (Cleared in K192197)	5.2, 6.2	4.5	-
	5.4, 6.4 (Newly Added)	4.3 (Newly Added)	
Magic Abutment (Screw type – Hex, Non-Hex, Cement type – Hex, Non-Hex) (Cleared in K192197)	4.27, 4.7, 5.21, 5.5, 6.0	4.5, 5.5, 6.5, 7.5, 8.5 4.6, 5.6, 6.6, 7.6, 8.6	-
	5.2, 5.7, 6.2, 6.7 (Newly Added)	4.51, 5.51, 6.5, 6.51, 7.5, 7.51, 8.5, 8.51, 10.5 (Newly Added)	
Magic UCLA Cement Retained Type (Cleared in K202418)	4.5, 5.2, 6.2	8.5, 8.75, 8.9, 10.2, 10.4, 10.5	-
		12.05, 12.85 (Length Change)	
Magicore Healing Cap (Cleared in K192197)	5.2, 6.2	4.5	-
	5.3, 5.8, 6.3, 6.8 (Newly Added)	2.8, 3.8, 4.8, 5.8, 6.8 (Newly Added)	
Magicore Healing Cap Screw	2.0	5.2, 7.1	-

(Cleared in K173120)		5.4, 6.4, 7.4, 8.4, 9.4 (Newly Added)	
Cylinder Screw (Cleared in K192197)	2.0	5.2, 7.1	-
		4.9 (Length Change), 7.1	

Abutments (Subject Device)	**Diameters (Ø)**	**Length (mm)**	**Angulation (°)**
Magic Multiunit Abutment (Screw type – Hex, Non-Hex, Cemented type – Hex, Non-Hex)	4.8, 5.8	2.3	0, 5, 10, 15, 20, 25
Magic Multiunit UCLA Cylinder	5.4, 6.4	11.2	-
Magic Cylinder	5.0, 6.0	10.6	-
Magic Multiunit Cylinder	5.0, 6.0, 5.4, 6.4	10	-
Magic Multiunit Cap	5.4, 6.4	4.3	-
Magic Abutment (Screw type – Hex, Non-Hex, Cement type – Hex, Non-Hex)	5.2, 5.7, 6.2, 6.7	4.51, 5.51, 6.5, 6.51, 7.5, 7.51, 8.5, 8.51, 10.5	-
Magic UCLA Cement Retained Type	4.5, 5.2, 6.2	12.05, 12.85	-
Magicore Healing Cap	5.3, 5.8, 6.3, 6.8	2.8, 3.8, 4.8, 5.8, 6.8	-
Magicore Healing Cap Screw	2.0	5.4, 6.4, 7.4, 8.4, 9.4	-
Cylinder Screw	2.0	4.9, 7.1	-

The subject abutments are compatible with the fixtures in this submission and the fixtures of K192197 and K201981.
The abutments are provided non-sterile and packaged separately. The abutments should be sterilized before use.

Summaries of Technology Characteristics:

1) Fixture

	Subject Device		**Primary predicate**			**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd		InnoBioSurg Co., Ltd			Dentis
Device Name	Magicore System		Magicore System			OneQ-SL s-Clean Implant System
510(k) No.	N/A		K201981			K153639
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 OneQ-SL s-Clean Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, 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.
Design						
	Cutting Edge, Non-Cutting Edge		Cutting Edge, Non-Cutting Edge			Cutting Edge
Composition of Material	Titanium Alloy Ti-6Al-4V Eli ASTM F136		Titanium Alloy Ti-6Al-4V Eli ASTM F136			CP Titanium Grade 4 (ASTM F67)
Connection	Internal Hex Non - Submerged		Internal Hex Non - Submerged			Internal Hex Submerged
Endosseous Implant	Tapered, macro threads		Tapered, macro threads			Tapered & Straight Body
Platform Diameters (Ø)	5.2	5.7	4.7	5.2	5.7	Regular: 3.7, 3.9, 4.2, 4.7, 5.2 Wide: 6.0, 7.0, 8.0
Fixture Diameters (Ø)	5.0, 5.5, 6.0, 6.5	7.0, 7.5, 7.8	4.0, 4.5, 5.0	4.0, 4.5	4.5, 5.0, 5.5, 6.0, 6.5	-

Cuff Lengths (mm)	1, 2, 3, 4		1, 2, 3, 4	-
Neck Lengths (mm)	2		2	
Implantable Lengths (mm)	7, 8, 9, 10, 11, 12, 13	7, 8, 9, 10	7, 8, 9, 10, 11, 12, 13	Regular: 7.8, 10, 12, 14 Wide: 7,8, 10, 12
Thread pitch	1.15P		1.15P	-
Modified Surface	R.B.M		R.B.M	S.L.A
Surgical Technique	1 and 2 stage, self-tapping		1 and 2 stage, self-tapping	3 sided cutting edge with self-tapping
Gamma Sterilization	Yes		Yes	Yes
SE Discussion	The Magicore System has same device characteristics with the Primary predicate (K201981) such as intended use, material, functions, general shape (Design), surface treatment, structure and applied production method. Platform/D 5.2 (Fixture/D 5.0,5.5,6.0.5,6.5) and P/D 5.7 (F/D 7.0,7.5,7.8) was added in the Primary predicate device. The subject fixture has bigger diameters such as 7.0, 7.5 and 7.8mm than the primary predicate. To support this discrepancy, the reference device, K153639 was added and the difference doesn't affect device's fundamental functions and safety since the diameter of the subject device is within the range of the reference device's diameters. Therefore, the subject device is substantial equivalent.			

2) Abutment

< Magic Multiunit Abutment (Screw type – Hex, Non-Hex & Cemented type – Hex, Non-Hex)>

	Subject Device	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore System	Magicore II System
Abutment Name	Magic Multiunit Abutment	Magic Multiunit Abutment
510(k) No.	NA	K201621
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design	 Hex  Non-Hex	 Hex  Non-Hex
Diameters (⌀)	4.8, 5.8	4.8, 5.8
Gingiva Height (mm)	2.3	1.5, 2.5, 3.5, 4.5
Angulation (°)	0	5, 10, 15, 20, 25
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The subject device is same in indications for Use, fundamental scientific technology, principle of operation, design, technology, functions, dimensions, and materials with the identified reference device. The Gingiva Height of previously cleared device (K201621) has changed. Also, the abutments with 0 º angulation are added to the previously cleared device. Since the primary predicate's abutment is worst case (largest angulation), this difference does not impact product's safety and effectiveness.	

<Magic Multiunit UCLA Cylinder>

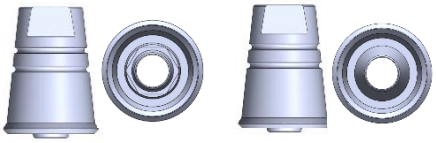
	Subject Device	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore System	Magic UCLA Abutment System
Abutment Name	Magic Multiunit UCLA Cylinder	Magic UCLA Screw Retained Type
510(k) No.	NA	K202418
Material	Co-Cr-Mo Alloy Poly Diacetate	Co-Cr-Mo Alloy Poly Diacetate
Design		
Diameters (⌀)	5.4, 6.4	4.5, 5.0, 5.2, 5.5, 6.0, 6.2, 6.3
Length (mm)	11.2	8.5, 8.75, 8.9, 10.2, 10.4, 10.5
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization

SE Discussion	The subject device is same in indications for use, material, fundamental scientific technology, principle of operation, design, technology, functions with the identified reference device. The differences between the subject and reference device are the design and dimensions. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.

<Magic Multiunit Cap>

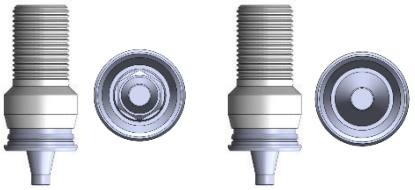
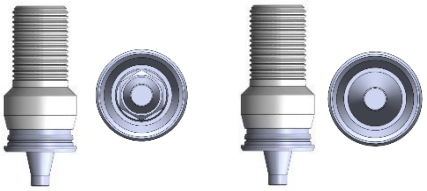
	Subject Device	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore System	Magicore II System
Abutment Name	Magic Multiunit Cap	Magic Multiunit Abutment Cap
510(k) No.	NA	K192197
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (⌀)	5.4, 6.4	5.2, 6.2
Length (mm)	4.3	4.5
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The subject device is same in indications for use, fundamental scientific technology, principle of operation, general design, technology, functions, and materials with the identified reference device. The differences between the subject and reference device are the design and dimensions. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

< Magic Abutment (Screw type- Hex, Non-Hex & Cemented type- Hex, Non-Hex)>

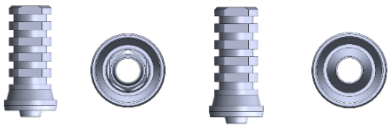
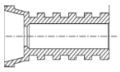
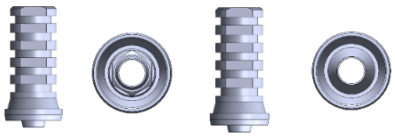
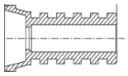
	Subject Device	**Reference Device**
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore System	Magicore II System
Abutment Name	Magic Abutment	Magic Abutment
510(k)	N/A	K192197
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design	 Hex Non-Hex	 Hex Non-Hex
Diameters (⌀)	5.2, 5.7, 6.2, 6.7	4.27, 4.7, 5.21, 5.5, 6.0
Lengths(mm)	4.51, 5.51, 6.5, 6.51, 7.5, 7.51, 8.5, 8.51, 9.5, 10.5	4.5, 5.5, 6.5, 7.5, 8.5 4.6, 5.6, 6.6, 7.6, 8.6

Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The subject device is same in indications for Use, fundamental scientific technology, principle of operation, general design, technology, functions, and materials with the identified reference device. The difference between the subject and reference device is the design and lengths of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

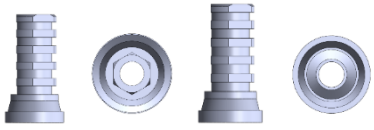
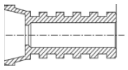
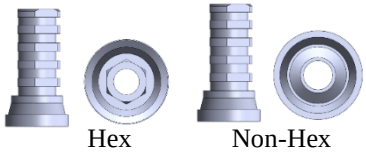
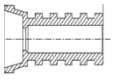
<Magic UCLA Cement Retained Type (Hex, Non-Hex)>

	Subject Device	**Primary Predicate**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore System	Magic UCLA Abutment System
Abutment Name	Magic UCLA Cement Retained Type	Magic UCLA Cement Retained Type
510(k) No.	NA	K202418
Material	Co-Cr-Mo Alloy Poly Diacetate	Co-Cr-Mo Alloy Poly Diacetate
Design	 Hex Non-Hex	 Hex Non-Hex
Diameters (⌀)	4.5, 5.2, 6.2	4.5, 5.0, 5.2, 5.5, 6.0, 6.2, 6.3
Length (mm)	12.05, 12.85	8.5, 8.75, 8.9, 10.2, 10.4, 10.5
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The subject device is same in indications for Use, fundamental scientific technology, principle of operation, general design, technology, functions, and materials with the identified reference device. The difference between the subject and reference device is the lengths of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

< Magic Cylinder (Hex, Non-Hex, Post)>

	Subject Device	**Primary Predicate**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore System	Magicore II System
Abutment Name	Magic Cylinder	Magic Multiunit Abutment ST
510(k) No.	NA	K201621
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design	 Hex Non-Hex  Post	 Hex Non-Hex  Post
Diameters (⌀)	5.0, 6.0	5.0, 6.0
Length (mm)	10.6	10
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The product name of the cleared Magic Multiunit Abutment ST (K201621) is changed into the Magic Cylinder. Also, the lengths of the Magic Cylinder is changed. The subject device is same in indications for Use, fundamental scientific technology, principle of operation, general design, technology, functions, and materials with the identified reference device. The difference between the subject and reference device is the lengths of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

<Magic Multiunit Cylinder (Hex, Non-Hex, Post)>

	Subject Device	**Primary Predicate**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore System	Magicore II System
Abutment Name	Magic Multiunit Cylinder	Magic Multiunit Cylinder
510(k) No.	NA	K201621
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design	 Hex Non-Hex  Post	 Hex Non-Hex  Post

Diameters (⌀)	5.0, 5.4, 6.0, 6.4	5.0, 6.0
Length (mm)	10	10
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The subject device is same in indications for Use, fundamental scientific technology, principle of operation, general design, technology, functions, and materials with the identified reference device. The difference between the subject and reference device is the diameters of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

<Magicore Healing Cap>

	Subject Device	**Primary Predicate**	**Reference Device**
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore System	Magicore II System	Magicore II System
Abutment Name	Magicore Healing Cap	Healing Cap	Magic Multiunit Abutment Cap
510(k) Number	N/A	K201981	K192197
Material	TI-6AL-4V ELI	TI-6AL-4V ELI	TI-6AL-4V ELI
Design			
Diameters (⌀)	5.3, 5.8, 6.3, 6.8	5.3, 5.5, 6.0, 6.3, 6.5, 6.9, 7.6	5.2, 6.2
Lengths(mm)	2.8, 3.8, 4.8, 5.8, 6.8	2.8, 4.2, 5.3	4.5
Surface Treatment	Machine-	Anodizing (Green, Purple, Blue, Yellow)	Machine
Sterilization	End user Sterilization	End user Sterilization	End user Sterilization
SE Discussion	The subject device is same in indications for Use, fundamental scientific technology, principle of operation, general design, technology, functions, and materials with the identified reference device. The difference between the subject and primary predicate device is the design and dimensions of the device. To support the design difference discrepancy, K192197 was added. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.		

<Magicore Healing Cap Screw>

	Subject Device	**Reference Device**
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore System	CCM Abutment System
Abutment Name	Magicore Healing Cap Screw	Abutment Screw
510(k) Number	N/A	K173120
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (⌀)	2.0	2.0
Lengths(mm)	5.4, 6.4, 7.4, 8.4, 9.4	5.2, 7.1
Surface Treatment	Machine	Machine
Sterilization	End user Sterilization	End user Sterilization
SE Discussion	The subject and Reference Device have similar indications for use, functions, materials, surface treatment, general shape (design). The difference between the subject and reference device is the design and lengths of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

<Cylinder Screw>

	Subject Device	**Reference Device**
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore System	Magicore II System
Abutment Name	Cylinder Screw	Abutment Screw
510(k) Number	N/A	K192197
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (⌀)	2.0	2.0
Lengths(mm)	4.9, 7.1	5.2, 7.1
Surface Treatment	Machine	Machine
Sterilization	End user Sterilization	End user Sterilization
SE Discussion	The subject and Reference Device have similar indications for use, functions, materials, surface treatment, general shape (design). The difference between the subject and reference device is the lengths of the device. However, it doesn't affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

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, general design, and dimensions. Any test reports of the predicate devices may be leveraged for the subject devices because they have the same materials, manufacturing methods, and sterilization procedures. Although the dimensions are slightly different, it does not impact the ability to determine substantial equivalence of the subject devices because the predicate 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 for devices provided sterile per ISO 11137-1 and ISO 11137-2 referenced in K192197
- LAL information/testing per USP <85> as referenced in K162099
- Shelf-Life Test on Fixtures according to ASTM F1980 referenced in K192197
- Biological assessment has been performed according to ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," and to the FDA Guidance document, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff
- End User Sterilization Validation Test Report according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1 referenced in K192197
- Fatigue test report for devices according to ISO 14801 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 required because the new worst case is not determined for the subject system.
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.