April 28, 2020

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

Re: K192197
Trade/Device Name: Magicore II System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 23, 2020
Received: April 27, 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)*
K192197

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
K192197

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Device Information

- Trade Name: Magicore II System
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date prepared: April 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
K072570, Nobelactive Multi Unit Abutment by Nobel Biocare AB
K080594, MS System (Narrow Ridge) by Osstem Implant Co., Ltd.
K150344, Dentis Dental Implant System by Dentis Co., Ltd.
K153350, IBS Implant System manufactured by InnoBioSurg Co., Ltd.
K160670, ET US SS Prosthetic system by Osstem Implant Co., Ltd.
K161689, OSSTEM Implant System – Abutment by Osstem Implant Co., Ltd.
K162099, IBS Implant System II manufactured by InnoBioSurg Co., Ltd.
K171027, Dentis Dental Implant System by Dentis Co., Ltd.
K173120, CCM Abutment System manufactured by InnoBioSurg Co., Ltd.
K173575, OsteoReady Dental Implant System by OsteoReady LLC.

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:

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 II 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 II implant is treated with SLA (sand-blasted, large-grit, acid-etched).
The Fixture diameters are 4.0, 4.5, 5.0, 5.5, 6.0, 6.5mm and threaded lengths are 7, 8, 9, 10, 11, 12, 13mm in this system.

The contained various abutments and screws in the system are Short Abutment, Magic Abutment, Magic Multi Abutment, Magic Multi Cylinder, Magic Multi Abutment ST, Abutment Screw, Healing Cap, Magicore Angled Abutment.
The dimension ranges of the abutments are below:

Abutments	Diameters (Ø)	Lengths (mm)
Short Abutment (Hex, Non-Hex)	3.5 , 3.86, 4.3, 4.6	4.55, 5.55, 6.55, 7.55, 8.55
Magic Abutment (Hex, Non-Hex)	4.57, 4.7, 5.07, 5.57, 5.7, 5.87, 6.2, 6.37, 6.5, 7.0	4.5, 5.5, 6.5, 7.5, 8.5
	4.27, 5.21, 5.5, 6.0	4.6, 5.6, 6.6, 7.6, 8.6
Magic Multi Abutment (Screw type – Hex, Non-Hex, Cemented type – Hex, Non-Hex)	4.8	4.6, 5.6, 6.6, 7.6, 8.6
		5, 6, 7, 8
		5.2, 6.2, 7.2, 8.2
	5.8	4.7, 5.7, 6.7, 7.7, 8.7
		5.1, 6.1, 7.1, 8.1
		5.3, 6.3, 7.3, 8.3
Magic Multi Cylinder (Hex, Non-Hex, Post)	5.0, 6.0	10
Magic Multi Abutment ST (Hex, Non-Hex, Post)	5.0, 6.0	10
Healing Cap	5.2, 6.2	4.5
Magicore Angled Abutment	4.3	11.2, 12.2, 13.2, 14.2
Abutment Screw	2	5.2, 7.1

Tolerance of dimension for Fixtures and Abutments shall be within ± 1% range.

Fixtures and abutments are packaged separately. The Fixtures are supplied sterile and the abutments and screw are provided non-sterile. The abutments and screw should be sterilized before use.

Materials:

- Fixtures are fabricated from Ti-6Al-4V Eli (Conforming to ASTM Standard F-136).
- Short Abutment, Magic Abutment, Magic Multi Abutment, Magic Multi Cylinder, Magic Multi Abutment ST, Abutment Screw, Healing Cap, Magicore Angled Abutment are fabricated from Ti-6Al-4V Eli (Conforming to ASTM Standard F-136).

Summaries of Technology Characteristics:

1) Fixture

	Subject Device	Primary Predicate	Reference Device		Reference Device
Product Name	Magicore II System	Magicore System	IBS Implant System II		MS System (Narrow Ridge)
510(k) Product code Class	N/A DZE II	K152520 DZE II	K162099 DZE II		K080594 DZE II
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd.		OSSTEM IMPLANT CO.,LTD
Indications 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 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.	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 MS System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. MS System (Narrow Ridge) are intended for single use only and not for immediate loading.
Design			 NR Fix	 Magic FC	
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		Titanium Alloy Ti-6Al-4V Eli ASTM F136

Connection	Internal Hex Non - Submerged	Internal Hex Non - Submerged	Internal Hex	-
Endosseous Implant	Tapered, macro threads	Tapered, macro threads	Tapered, macro threads	Micro threaded, One Body Implant
Range of Diameters (mm)	4.0, 4.5, 5.0, 5.5, 6.0, 6.5mm	4.0, 4.5, 5, 5.5, 6, 6.5mm	NR Fix : 3.5 and 3.8 Magic FC : 4.0, 4.5, 5.0, 5.5, 6.0, 6.5mm	3.0mm
Range of Lengths (mm)	7, 8, 9, 10, 11, 12, 13mm	7, 9, 11, 13mm	NR Fix 3.5 : 9, 11 13 NR Fix 3.8: 7, 10, 11, 12, 13, 14, 15mm Magic FC : 7, 9, 11, 13, 15mm	10, 11.5, 13, 15mm
Modified Surface	S.L.A	R.B.M	S.L.A	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	1 stage and 2 stage, self tapping
Gamma Sterilization	Yes	Yes	Yes	Yes
Principle Operation	Dental implant that can be inserted on a jawbone as a material for dental surgery to support	Dental implant that can be inserted on a jawbone as a material for dental surgery to support	Dental implant that can be inserted on a jawbone as a material for dental surgery to support	Dental implant that can be inserted on a jawbone as a material for dental surgery to support
Similarities	The Magicore II System has same device characteristics with the Primary predicate devices, Magicore system (K152520) such as diameters, Length, intended use, material, functions, general shape (Design), structure and applied production method are similar.			
Differences	The differences between the subject device and the primary predicate device is the dimension and surface treatment. Compared to the primary predicate device, the subject device includes more variable length implants than the primary predicate device such as 8,10,12mm. But the range of the diameters are same from 7 to 13mm, which doesn't raise any questions about safety and effectiveness. K162099 was added as reference device to support the surface treatment of SLA for subject device. The differences between the subject device and predicate device (K080594) is range of Diameters and Lengths but it was added as reference device to support the subject device which has 4mm cuff height.			

2) Abutments

<Short Abutment (Hex, Non-Hex)>

	Subject Device	Reference Device	Reference Device
Company	InnoBioSurg Co., Ltd.	Dentis Co., Ltd.	OsteoReady LLC
Device Name	Magicore II System	Dentis Dental Implant System	OsteoReady Dental Implant System
510(k)	N/A	K171027	K173575
Indications 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 Dentis Dental Implant System is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.	OsteoReady® Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. RidgeReady® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.
Material	TI-6AL-4V ELI	Pure Titanium(Grade 4)	Ti-6Al-4V-ELI
Design			
Diameters (Ø)	3.5, 3.86, 4.3, 4.6	3.5	4.5
Lengths(mm)	4.55, 5.55, 6.55, 7.55, 8.55	8.3	5,7,9,12
Surface Treatment	Machine-	Machine-	Machine-
Sterilization	End User Sterilization	Steam sterilization by user	End User Sterilization
Principle of Operation	Has one component to engage anti rotational hex of implant body and the other component to fixate the abutment and implant body together.	Conventional procedure	Conventional procedure
SE Discussion	There is no similar product as the subject short abutment in the primary predicate, K152520. So, K171027 was added as reference device. Both subject device and K171027 have similar indication for use and same functions, surface treatment, and general shape (design). The difference between subject and K171027 is material and dimensions. To support the discrepancy, K173575 was added and the difference doesn't affect device's fundamental functions and safety.		

< Magic Abutment (Hex, Non-Hex)>

	Subject Device	Reference Device
Company	InnoBioSurg Co., Ltd.	Osstem Co., Ltd.
Device Name	Magicore II System	SS System
510(k) Number	N/A	K160670
Indications 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.	ET System The HIOSSEN Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures. US/SS System The OSSTEM Prosthetic system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (Ø)	4.27, 4.57, 4.7, 5.07, 5.2, 5.21, 5.5, 5.57, 5.7, 5.87, 6.0, 6.2, 6.37, 6.5, 7.0	4.8, 6.0
Lengths(mm)	4.5, 5.5, 6.5, 7.5, 8.5 4.6, 5.6, 6.6, 7.6, 8.6	6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
Principle of Operation	Has one component to engage anti rotational hex of implant body and the other component to fixate the abutment and implant body together.	As general cement retained restoration, it is connected with fixture and cemented crown on the abutment
SE Discussion	There is no similar product as the subject magic abutment in the primary predicate, K152520. So, K160670 was added as reference device. Both subject device and K160670 have similar indication for use and same functions, material, surface treatment, and general shape (design). The difference between subject and K160670 is dimensions. However, the difference doesn't affect device's fundamental functions and safety.	

<Magic Multi Abutment (Hex, Non-Hex)>

	Subject Device	Reference Device
Company	InnoBioSurg Co., Ltd.	Nobel Biocare AB
Device Name	Magicore II System	Nobel Biocare Multi unit Abutment
510(k) Number	N/A	K072570
Indications 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.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation
Material	TI-6AL-4V ELI	----
Design		
(Abutment) Diameters (Ø)	4.8, 5.8	3.5, 4.3
Gingiva Height (mm)	1.5, 2.5, 3.5, 4.5	----
Angulation (°)	15, 25°	17, 30°
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	Gamma Sterilization
Principle of Operation	Used in screw retained and cement retained restoration. Magic Multi Abutment should be placed into patient's mouth before taking impression.	Used in screw retained restoration only. Multi unit Abutment should be placed into patient's mouth before taking impression.
SE Discussion	There is no similar product as the subject magic multi abutment in the primary predicate, K152520. So, K072570 was added as reference device. Both subject device and K072570 have similar indication for use and same functions, material, surface treatment, and general shape (design). The difference between the subject and predicate devices are gingiva height and angulations. The gingiva height of the subject device are shorter than the predicate device. The angulations are different between subject and predicate devices; however, it doesn't affect device's fundamental functions since the angulation of the subject device is smaller than the predicate's.	

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

	Subject Device	Reference Device
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore II System	IBS Implant System II
510(k) Number	N/A	K162099
Indications 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 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.
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (Ø)	5.0, 6.0	3.5, 4.0, 4.5, 5.0, 5.5, 6.0
Lengths(mm)	10	12
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
Principle of Operation	Cylinders are used in conjunction with screw retained type Abutment to provide support for screw type final prosthesis, and for fabrication of custom abutment for screw retained restorations.	Cylinders are used in conjunction with screw retained type Abutment to provide support for screw type final prosthesis, and for fabrication of custom abutment for screw retained restorations.
SE Discussion	There is no similar product as the subject magic multi Cylinder in the primary predicate, K152520. So, K162099, our own predicate was added as reference device. Both subject device and K162099 have similar indication for use and same functions, material, surface treatment, and general shape (design). The difference between the subject and predicate device is the length of the device. However, it doesn't affect device's fundamental functions and safety.	

< Magic Multi Abutment ST (Hex, Non-Hex, Post)>

	Subject Device	Reference Device
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore II System	IBS Implant System II
510(k) Number	N/A	K162099
Indications 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 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.
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (Ø)	5.0, 6.0	3.5, 4.0, 4.5, 5.0, 5.5, 6.0
Lengths(mm)	10	12
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
Principle of Operation	The abutments are fixed to the underlying implant with an abutment screw.	The abutments are fixed to the underlying implant with an abutment screw.
SE Discussion	There is no similar product as the subject magic multi abutment ST in the primary predicate, K152520. So, K162099, our own predicate was added as reference device. Both subject device and K162099 have similar indication for use and same functions, material, surface treatment, and general shape (design). The difference between the subject and predicate device is the length of the device. However, it doesn't affect device's fundamental functions and safety.	

<Healing Cap>

	Subject Device	Reference Device	Reference Device
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.	DENTIS CO., LTD.
Device Name	Magicore II System	IBS Implant System	Dentis Dental Implant System
510(k) Number	N/A	K153350	K150344
Indications 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 IBS Implant System is intended to replace missing teeth to restore chewing function. The IBS Implant can be placed in support of single or multi-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 surgical procedure. This system is intended for delayed loading.	The Dentis Dental Implant System is an endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted interforminal placed implants.
Material	TI-6AL-4V ELI	Titanium Gr 4	TI-6AL-4V ELI
Design			
Diameters (Ø)	5.2, 6.2	5.35	5.4
Lengths(mm)	4.5	4.95	5.0
Surface Treatment	Machine	Machine	Machine
Sterilization	End user Sterilization	End user Sterilization	End user Sterilization
Principle of Operation	Healing caps lead to accurate closure of soft tissue surrounding implant and provide a definite shape and form to gingiva which is aesthetically close to natural look.	Healing caps lead to accurate closure of soft tissue surrounding implant and provide a definite shape and form to gingiva which is aesthetically close to natural look.	Conventional procedure
SE Discussion	There is no similar product as the subject healing cap in the primary predicate, K152520. So, K153350, our own predicate was added as reference device. Both subject device and K153350 have same indication for use, functions, surface treatment, and general shape (design). The difference between subject and K153350 is material and dimensions. To support the discrepancy, K150344 was added and the difference doesn't affect device's fundamental functions and safety.		

<Magicore Angled Abutment>

	Subject Device	Reference Device
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore II System	IBS Implant System
510(k) Number	N/A	K153350
Indications 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 IBS Implant System is 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.
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (Ø)	4.3	4, 4.5, 5
Lengths(mm)	11.2, 12.2, 13.2, 14.2	---
Angulation (°)	15°, 25°	15º, 25º, 30º
Surface Treatment	Machine	Machine
Sterilization	End User Sterilization	End User Sterilization
Principle of Operation	Used to fixate the abutment and implant body together.	Used to fixate the abutment and implant body together.
SE Discussion	There is no similar product as the subject magic multi abutment in the primary predicate, K152520. So, K153350, our own predicate was added as reference device. Both subject device and K153350 have similar indication for use and same functions, material, surface treatment, and general shape (design). The differences between the subject and predicate device are the design of the device. However, it doesn't affect device's fundamental functions and safety.	

<Abutment Screw>

	Subject Device	Reference Device	Reference Device
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.	OSSTEM Implant Co., Ltd
Device Name	Magicore II System	CCM Abutment System	OSSTEM Implant System - Abutment
510(k) Number	N/A	K173120	K161689
Indications 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 CCM Abutment System is intended to replace missing teeth to restore chewing function. The CCM Abutment System can be placed in support of single or multiple-unit restorations including; cement retained, screw retained, 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 OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures
Material	TI-6AL-4V ELI	TI-6AL-4V ELI	Ti-6Al-4V
Design			
Diameters (Ø)	2.0	2.0	2.0, 2.05, 2.2, 2.3, 2.5
Lengths(mm)	5.2, 7.1	7	3.35, 5.6, 7.5, 8.35, 9.6, 10.2
Surface Treatment	Machine	Machine	Machine
Sterilization	End user Sterilization	End user Sterilization	End user Sterilization
Principle of Operation	Connection body to connect abutment to fixture.	Connection body to connect abutment to fixture.	Used to connect an abutment with fixture.
Similarities	The subject and Predicate device have same indications for use, functions, materials, surface treatment, general shape (design).		
Differences	There is no similar product as the subject Abutment screw in the primary predicate, K152520. So, K173120, our own predicate was added as reference device. Both subject device and K173120 have same indication for use, functions, material, surface treatment, and general shape (design). The difference between subject and K173120 is lengths. To support the discrepancy, K161689 was added and the difference doesn't affect device's fundamental functions and safety since the length of subject device is within the range of the reference device's lengths.		

Non-Clinical Data:

Fatigue Testing according to ISO 14801:2016 was performed on the subject device under the worst-case scenario and its result is strong enough to achieve their intended use.

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

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 K152520.
- LAL information/testing per USP <85> as referenced in K162099
- Shelf Life Test on Healing Abutments according to ASTM F1980 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, K152520 and K162099
- Biocompatibility testing according to ISO 10993-1:2009, ISO 10993-5:2009, ISO10993-6:2007, and ISO 10993-10:2010 on abutments referenced in K152520 and K173120

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". The surface treatment analysis was used to support the decision of substantial equivalence.

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.