December 14, 2022

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

Re: K220079
Trade/Device Name: Magicore Narrow System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 10, 2022
Received: November 14, 2022

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,

Andrew I. Steen -S

Andrew I. 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)*
K220079

Device Name
Magicore Narrow System

Indications for Use *(Describe)*
The Magicore Narrow System (3.0, 3.5mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
The implants may be restored immediately
1) with a temporary prosthesis that is not in functional occlusion,
2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or
3) for denture stabilization using multiple implants in the anterior mandible and maxilla.
The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal 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 Narrow 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: 12/13/2022

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

Primary Predicate
K161244, s-Clean OneQ-SL Narrow Implant System manufactured by Dentis Co., Ltd.

Reference Device
K093321, BioHorizons Laser-Lok 3.0 Implant System by BioHorizons Implant
K152520, Magicore System manufactured by InnoBioSurg Co., Ltd.
K173120, CCM Abutment System manufactured by InnoBioSurg Co., Ltd.
K192197, Magicore II System manufactured by InnoBioSurg Co., Ltd.
K201981, Magicore System manufactured by InnoBioSurg Co., Ltd.
K212517, Magicore System manufactured by InnoBioSurg Co., Ltd.

Indications for Use
The Magicore Narrow System (3.0, 3.5mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
The implants may be restored immediately
1) with a temporary prosthesis that is not in functional occlusion,
2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or
3) for denture stabilization using multiple implants in the anterior mandible and maxilla.
The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.

Device Description:
The fixtures and abutments in this system are below:

1) Fixture
   - Magicore Narrow (RBM)
   - Magicore Narrow (SLA)

2) Abutment
   - Short Abutment(Hex, Non-Hex)
   - Magicore Solid Abutment
   - Magic Abutment (Hex, Non-Hex)
   - Magicore Solid Abutment Cap
   - Magicore Healing Cap
   - Magicore Healing Cap Screw
   - Closing Screw
   - Abutment 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 Narrow 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 Narrow implant is treated with RBM (Resorbable Blasted media) or SLA(sand-blasted, large-grit, acid-etched).

Below is the fixture dimension range:

Fixture	Fixture Diameters (Ø) X Implantable Lengths (mm)
Magicore Narrow - RBM	3.0(Ø) X 11.0, 13.0, 15.0 (mm) 3.5(Ø) X 11.0, 13.0, 15.0 (mm)
Magicore Narrow -SLA	3.0(Ø) X 11.0, 13.0, 15.0 (mm) 3.5(Ø) X 11.0, 13.0, 15.0 (mm)

The subject fixtures are provided sterile.

Below is the abutment Features and dimension range:

Abutments	Uses	Diameters (Ø)	Length (mm)	Angle (˚)	Surface Treatment
Closing Screw	Closing Screw is placed flush over the top of the implant and the gum is sewn up over it for the period of healing.	2.75	5.2	0	Anodizing
Short Abutment(Hex, Non-Hex)	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	2.8	4.2, 5.2, 6.2, 7.2, 8.2	0	N/A
Magic Abutment(Hex, Non-Hex)	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	3.87	4.2, 5.2, 6.2, 7.2, 8.2	0	N/A
	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	4.5	4.2, 5.2, 6.2, 7.2, 8.2	0	N/A

Magicore Solid Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	2.8	7.2, 8.2, 9.2, 10.2, 11.2	0	N/A
Magicore Solid Abutment Cap	The Abutment used to protect abutment inside of the mouth and minimize the feeling of irritation from the patient's mouth.	4.5	5.5, 6.5, 7.5, 8.5, 9.5	0	N/A
Magicore Healing Cap	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.	4.6, 4.8	5.5, 7.1, 8.0	0	N/A
Magicore Healing Cap Screw	Connection body to connect abutment to fixture.	1.8	6.4	0	N/A
Abutment Screw	Connection body to connect abutment to fixture.	1.8	7.0	0	N/A

The Closing Screw, Magicore Healing Cap are supplied sterile by Gamma sterilization. Other abutments are provided non-sterile and packaged separately. The abutments should be sterilized before use by End User sterilization.

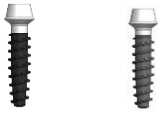
The Magicore Narrow Fixture is only compatible with the Magicore Narrow Abutments.

Materials:

- Magicore Narrow Fixture and abutments are made of Ti-6Al-4V Eli
- Magicore Solid Abutment Cap is made of PolyOxyMethylene(=Acetal)

Summaries of Technological Characteristics & Substantial Equivalence Discussion

Fixtures

	Subject Device	**Primary predicate**	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd	Dentis Co., Ltd.	BioHorizons Implant Systems, Inc
Device Name	Magicore Narrow System	s-Clean OneQ-SL Narrow Implant System	BioHorizons Laser-Lok 3.0 Implant System
510(k) No.	K220079	K161244	K093321
Indications for use	The Magicore Narrow System (3.0, 3.5mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.	The s-Clean OneQ-SL Narrow Implant System (3.0, 3.3mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.	BioHorizons Laser-Lok 3.0 Implants may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.
Design	 RBM SLA		
	Non-Cutting Edge	Cutting Edge	Non-Cutting Edge
Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Connection	Internal Hex Non - Submerged	Internal Hex	Internal Hex
Endosseous Implant	Tapered, macro threads	Tapered, macro threads	Tapered, macro threads
Platform Diameters	Ø 4.0	-	-
Fixture Diameters	Ø 3.0, Ø 3.5	Ø 3.0, Ø 3.3	Ø 3.0
Implantable Lengths	11.0, 13.0, 15.0 mm	10.0, 12.0, 14.0 mm	10.5, 12.0, 15.0 mm
Modified Surface	R.B.M & S.L.A	S.L.A	R.B.M

Surgical Technique	1 and 2 stage, self-tapping	1 and 2 stage, self-tapping	1 and 2 stage, self-tapping
Gamma Sterilization	Yes	Yes	Yes
SE Discussion	The Magicore Narrow System has similar device characteristics with the Primary predicate such as Indications for use, functions, material, surface treatment (SLA), fixture diameter, surgical technique, sterilization method, structure and applied production method. The difference between the subject device and primary predicate are device design, the longest implantable length and surface treatment (RBM) of the device. To support the Ø3.0 X15mm and the Ø3.5 X15mm long length and surface treatment (RBM), K093321 was added as reference device. Any differences do not raise different questions of safety and effectiveness than the primary predicate; therefore, it is substantial equivalent.		

Abutment

<Closing Screw>

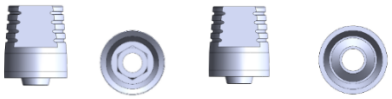
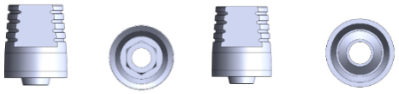
	Subject Device	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore Narrow System	Magicore System
Abutment Name	Closing Screw	Closing Screw
510(k) No.	K220079	K152520
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (⌀)	2.75	3.5
Total Length (mm)	5.2	5.65
Surface Treatment	Anodizing (Light Green)	Machined & Anodizing (Yellow, Purple, Blue, Green)
Sterilization	Gamma Sterilization	Gamma Sterilization
SE Discussion	The subject device is similar in intended use, fundamental scientific technology, principle of operation, general design, technology, functions, material, anodizing with the cover screw cleared in K152520. The difference between the subject and reference device is dimension of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

< Short Abutment (Hex, Non-Hex)>

	Subject Device	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore Narrow System	Magicore II System
Abutment Name	Short Abutment	Short Abutment
510(k) No.	K220079	K192197
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design	 Hex Non-Hex	 Hex Non-Hex

Diameters (⌀)	2.8	3.5, 3.86, 4.3, 4.6
Total Length (mm)	4.2, 5.2, 6.2, 7.2, 8.2	4.55, 5.55, 6.55, 7.55, 8.55
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The subject device is similar in intended use, fundamental scientific technology, principle of operation, design, technology, functions, dimensions, and materials with the identified reference device. The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

< Magic Abutment (Hex, Non-Hex)>

	Subject Device	**Reference Device**
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore Narrow System	Magicore II System
Abutment Name	Magic Abutment	Magic Abutment
510(k)	K220079	K192197
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design	 Hex Non-Hex	 Hex Non-Hex
Diameters (⌀)	3.87	4.57, 4.7, 5.07, 5.57, 5.7, 5.87, 6.2, 6.37, 6.5, 7.0
Total Lengths(mm)	4.2, 5.2, 6.2, 7.2, 8.2	4.27, 5.21, 5.5, 6.0
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The subject device is similar in intended use, fundamental scientific technology, principle of operation, design, technology, functions, dimensions, and materials with the identified reference device. The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent. SMAH5506AS	

	Subject Device	**Reference Device**
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore Narrow System	Magicore System
Abutment Name	Magic Abutment	Magic Abutment
510(k)	K220079	K212517
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design	 Hex Non-Hex	 Hex Non-Hex
Diameters (⌀)	4.5	5.2, 5.7, 6.2, 6.7
Total Lengths(mm)	4.2, 5.2, 6.2, 7.2, 8.2	4.51, 5.51, 6.5, 6.51, 7.5, 7.51, 8.5, 8.51, 9.5, 10.5
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization

SE Discussion	The subject device is similar in intended use, fundamental scientific technology, principle of operation, design, technology, functions, dimensions, and materials with the identified reference device. The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.

< Magicore Solid Abutment>

	Subject Device	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore Narrow System	Magicore System
Abutment Name	Magicore Solid Abutment	Magicore Solid Abutment
510(k) No.	K220079	K201981
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (⌀)	2.8	3.5, 3.86, 4.3, 4.6
Total Length (mm)	7.2, 8.2, 9.2, 10.2, 11.2	7.6, 8.6, 9.6, 10.6, 11.6
Surface Treatment	Machine-	Machine-
Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The subject device is similar in intended use, fundamental scientific technology, principle of operation, design, technology, functions, dimensions, and materials with the identified reference device. The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

<Magicore Solid Abutment Cap>

	Subject Device	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore Narrow System	Magicore System
Abutment Name	Magicore Solid Abutment Cap	Magicore Solid Abutment Cap
510(k) No.	K220079	K201981
Material	PolyOxyMethylene (=Acetal)	PolyOxyMethylene (=Acetal)
Design		
Diameters (⌀)	4.5	5.5, 6.0, 6.5, 7.0
Total Length (mm)	5.5, 6.5, 7.5, 8.5, 9.5	5.5, 6.5, 7.5, 8.5, 9.5
Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The subject device is similar in intended use, fundamental scientific technology, principle of operation, design, technology, functions, dimensions, and materials with the identified reference device. The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

<Magicore Healing Cap>

	Subject Device	**Reference Device**
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore Narrow System	Magicore System
Abutment Name	Magicore Healing Cap	Healing Cap
510(k) Number	K220079	K201981
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (⌀)	4.6, 4.8	5.3, 5.5, 6.0, 6.3, 6.5, 6.9, 7.6
Total Lengths(mm)	5.5, 7.1, 8	4.5
Surface Treatment	Machine-	Anodizing (Green, Purple, Blue, Yellow)
Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The subject device is similar in intended 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 dimensions and surface treatment of the device. 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 Narrow System	CCM Abutment System
Abutment Name	Magicore Healing Cap Screw	Abutment Screw
510(k) Number	K220079	K173120
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (⌀)	1.8	2.0
Total Lengths(mm)	6.4	5.2, 7.1
Surface Treatment	Machine	Machine
Sterilization	End user Sterilization	End user Sterilization
SE Discussion	The subject device is similar in intended use, fundamental scientific technology, principle of operation, design, technology, functions, dimensions, and materials with the identified reference device. The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

<Abutment Screw>

	Subject Device	**Reference Device**
Company	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	Magicore Narrow System	CCM Abutment System
Abutment Name	Abutment Screw	Abutment Screw
510(k) Number	K220079	K173120
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (⌀)	1.8	2.0
Total Lengths(mm)	7	5.2, 7.1
Surface Treatment	Machine	Machine
Sterilization	End user Sterilization	End user Sterilization
SE Discussion	The subject device is similar in intended use, fundamental scientific technology, principle of operation, design, technology, functions, dimensions, and materials with the identified reference device. The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

Non-Clinical Data:

Below tests were performed on subject device:

- Shelf Life for subject fixtures according to ASTM F1980

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

- Sterilization validation for subject fixtures according to ISO 11137-1 and ISO 11137-2 referenced in K162099 & K140806
- LAL information/testing for subject fixtures according to USP <85> as referenced in K140806 & K162099
- 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 for subject abutments made of Titanium ELI referenced in K202479
- 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 for subject abutments made of PolyOxyMethylene referenced in K140806
- Biocompatibility testing for subject Fixtures 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 referenced in K140806 & K162099
- Biocompatibility testing for subject abutments made of Titanium ELI according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-6:2007, and ISO 10993-10:2010 referenced in K140806

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) and SLA(sand-blasted, large-grit, acid-etched)was provided. To compare surface modification between the subject and predicate

devices, K152520 and K192197, surface roughness, surface composition analysis, and SEM imaging were provided, and it demonstrate the substantial equivalence.
The Sterilization validation test were performed on K140806 and K162099 for fixtures and cover screws with the same material, sterilization method, packaging method, and manufacturing process as the subject device.
The end user sterilization test was performed for predicate device and leveraged for the subject device because the product category, material, manufacturing process, facility, and packaging of both products are exactly same.
The Biocompatibility Test was conducted on the predicate device and leveraged for the subject device because both products are manufactured with same materials and manufacturing process. It demonstrates that the subject device is biocompatible and substantial equivalence with the predicate.

- MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the Magicore Narrow System devices in the MRI environment using scientific rationale and published literature (e.g.,Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

- Performance testing of Fixture Packaging

Below performance testing and information have been provided for subject implant fixture packaging:

- Human Factors testing (A usability evaluation for aseptic presentation of the subject device, in line with ISO 11607-1:2019 and the recommendations of the FDA guidance document, "Applying Human Factors and Usability Engineering to Medical Devices.")
- Low and high magnification images at various degrees of rotation following the removal from the packaging (Evaluation of the broken tip at various degrees rotation at a high magnification and low magnification for damage after removal from the packaging and disconnection of the fixture jig)
- Quality System (QS) plan including the method and frequency of acceptance activities to ensure that the devices conform with product specifications with packaging design.

Conclusion
The Magicore Narrow 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 Narrow System and its predicates are substantially equivalent.