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

12/20/22

Re: K220517
Trade/Device Name: IBS System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 21, 2022
Received: November 21, 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,

Sherrill Lathrop Blitzer

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)*
K220517

Device Name
IBS System

Indications for Use *(Describe)*
The IBS System is intended to replace missing teeth to restore chewing function. The IBS 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

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Device Information

- Trade Name: IBS 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: 12/20/2022

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

Primary Predicate
K212517, Magicore System by InnoBioSurg Co., Ltd.

Reference Device
K152520, Magicore System by InnoBioSurg Co., Ltd.
K173120, CCM Abutment System by InnoBioSurg Co., Ltd.
K181138, CMI Implant IS System by Neobiotech Co. Ltd.
K182448, AnyRidge Octa 1 Implant System by MegaGen Implant Co. Ltd.
K192197, Magicore II System by InnoBioSurg Co., Ltd.
K200753, IBS Implant System II by InnoBioSurg Co., Ltd.

Indication for Use:
The IBS System is intended to replace missing teeth to restore chewing function. The IBS 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

The fixtures and abutments in this system are below:

1) Fixture
   - Magicore (RBM)
   - Magicore (RBM Cutting Edge)
   - Magicore II (SLA)
   - Magicore II (SLA Cutting Edge)
2) Abutment
   - Magic Angled Abutment (Screw type _Hex, Non-Hex)
   - Magic Motion
   - Magic Motion Housing
   - Magic Abutment (Screw type_Hex, Non-Hex & Cement type_Hex, Non-Hex)
   - Magic Multiunit Abutment (Cement type_Hex, Non-Hex)
   - Magic Multiunit Cap

An endosseous dental implant is a device made of a material such as Ti-6AL-4V Eli (Conforming to ASTM Standard F-136). The implant-abutment connection is tight and precise fitting with internal hex, non-hex and Morse taper bevel. The surface of the Magicore implant is treated with RBM (Resorbable Blasted media) and Magicore II implants are treated with SLA(sand-blasted, large-grit, acid-etched).

Below is the fixture dimension range:

Fixture	Platform Diameters (Ø)	Fixture Diameters (Ø)	Cuff Lengths (mm)	Implantable Lengths (mm)
Magicore (RBM) Magicore (RBM _ Cutting Edge)	5.7	7.0	1.0, 2.0, 3.0, 4.0	11.0 ,12.0 ,13.0
		7.5		10.0, 11.0, 12.0, 13.0
		8.0		9.0, 10.0, 11.0, 12.0, 13.0
Magicore II (SLA) Magicore II (SLA _ Cutting Edge)	5.7	7.0, 7.5, 8.0	1.0, 2.0, 3.0, 4.0	7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0

The subject fixtures are provided sterile.

Below is the abutment dimension range:

Abutments	Uses	Diameter (Ø)	Total Length (mm)	Angle(˚)	Surface
Magic Angled Abutment (Screw type _ Hex, Non-Hex)	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	5.3	8.45, 8.96, 9.45, 9.96, 10.45, 10.96, 11.45, 11.96	15, 23	machined
		6.3	8.68, 9.32, 9.68, 10.32, 10.68, 11.32, 11.68, 12.32		
Magic Motion	The Magic Motion Abutment is connected with fixture and replace missing teeth to restore chewing function.	4.0	10.61, 11.11, 11.56, 12.06, 12.11, 13.06, 13.11, 14.06, 14.11, 15.06	-	machined
Magic Motion Housing	The Magic Motion Housing is connected with magic motion and replace missing teeth to restore chewing function.	5.16	3.3	-	machined

Magic Abutment (Screw type _ Hex, Non-Hex)	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	5.2, 5.7, 6.2, 6.7	4.51, 5.51, 6.51, 7.51, 8.51	-	RBM (Blasting)
Magic Abutment (Cement type _ Hex, Non-Hex)	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	5.2, 5.7, 6.2, 6.7	6.5, 7.5, 8.5, 9.5, 10.5	-	RBM (Blasting)
Magic Multiunit Abutment (Cement type _ Hex, Non-Hex)	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	4.8	5.7, 6.7, 7.7, 8.7	0, 5,10	RBM (Blasting)
			5.66, 6.66, 7.66, 8.66	15	
			6.0, 7.0, 8.0, 9.0	20	
			6.237, 7.237, 8.237, 9.237	25	
		5.8	5.76, 6.76, 7.76, 8.76	0, 5, 10	
			5.69, 6.69, 7.69, 8.69	15	
			5.96, 6.96, 7.96, 8.96	20	
			6.344, 7.334, 8.334, 9.344	25	
Magic Multiunit Cap	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.	5.4, 6.4	4.3	-	RBM (Blasting)

The abutments are provided non-sterile and packaged separately. The abutments should be sterilized before use by End User sterilization.

Materials:

- The Magicore, Magicore II fixtures, Magic Angled Abutment, Magic Motion Housing, Magic Abutment, Magic Multiunit Abutment and Magic Multiunit cap are made of Ti-6Al-4V ELI
- The Ball Pin of the Magic Motion is made of Ti-6Al-4V ELI and the body of the Magic Motion is made of Co-Cr-Mo Alloy.

Summaries of Technological Characteristics & Substantial Equivalence Discussion

1) Magicore and Magicore II Fixtures

<table>
<tr><th></th><th colspan="2">Subject Device</th><th colspan="2">Primary predicate</th><th>Reference predicate</th></tr>
<tr><td>Manufacturer</td><td colspan="2">InnoBioSurg Co., Ltd</td><td colspan="2">InnoBioSurg Co., Ltd</td><td>InnoBioSurg Co., Ltd</td></tr>
<tr><td>Device Name</td><td colspan="2">IBS System</td><td colspan="2">Magicore System</td><td>Magicore II System</td></tr>
<tr><td>510(k) No.</td><td colspan="2">K220517</td><td colspan="2">K212517</td><td>K192197</td></tr>
<tr><td>Indications for use</td><td colspan="2">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. This system is intended for delayed loading.</td><td colspan="2">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.</td><td>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 multipleunit 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</td></tr>
<tr><td rowspan="2">Design</td><td> 
Magicore</td><td> 
Magicore II</td><td colspan="2">  </td><td>  </td></tr>
<tr><td colspan="2">Cutting Edge
Non-Cutting Edge</td><td colspan="2">Cutting Edge
Non-Cutting Edge</td><td>Cutting Edge
Non-Cutting Edge</td></tr>
<tr><td>Material</td><td colspan="2">Ti-6Al-4V Eli</td><td colspan="2">Ti-6Al-4V Eli</td><td>Ti-6Al-4V Eli</td></tr>
<tr><td>Connection</td><td colspan="2">Internal Hex
Non - Submerged</td><td colspan="2">Internal Hex
Non - Submerged</td><td>Internal Hex
Non - Submerged</td></tr>
<tr><td>Endosseous Implant</td><td colspan="2">Tapered, macro threads</td><td colspan="2">Tapered, macro threads</td><td>Tapered, macro threads</td></tr>
<tr><td>Platform Diameters (Ø)</td><td colspan="2">5.7</td><td>5.2</td><td>5.7</td><td>4.7, 5.2, 5.7</td></tr>
<tr><td>Fixture Diameters (Ø)</td><td colspan="2">7.0, 7.5, 8.0</td><td>5.0, 5.5, 6.0, 6.5</td><td>7.0, 7.5, 7.8</td><td>4.0, 4.5, 5.0, 5.5, 6.0, 6.5</td></tr>
<tr><td>Cuff Lengths (mm)</td><td colspan="2">1.0, 2.0, 3.0, 4.0</td><td colspan="2">1.0, 2.0, 3.0, 4.0</td><td>0, 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0</td></tr>
<tr><td rowspan="3">Implantable Lengths (mm)</td><td>11.0, 12.0, 13.0</td><td rowspan="3">7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0</td><td rowspan="3">7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0</td><td rowspan="3">7.0, 8.0, 9.0, 10.0</td><td rowspan="3">7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0</td></tr>
<tr><td>10.0, 11.0, 12.0, 13.0</td></tr>
<tr><td>9.0, 10.0, 11.0, 12.0, 13.0</td></tr>
<tr><td>Surface Treatment</td><td>R.B.M</td><td>S.L.A</td><td colspan="2">R.B.M</td><td>S.L.A</td></tr>
</table>

Surgical Technique	1 and 2 stage, self-tapping	1 and 2 stage, self-tapping	1 stage and 2 stage, self tapping
Gamma Sterilization	Yes	Yes	Yes
SE Discussion	The subject IBS System has same indications for Use, material, surface treatment, connection, general shape (Design), surface structure, applied production method and surgical technique as the Primary Predicate, K212517. For SLA surface treatment and Magicore II fixture's design of the subject device, K192197 was added as a reference device. Therefore, subject device and predicate devices are substantially equivalent.		

2) Abutment

<Magic Angled Abutment (Screw type _Hex, Non-Hex)>

	Subject Device		**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.		Neobiotech Co., Ltd.
Device Name	IBS System		CMI Implant IS System
Abutment Name	Magic Angled Abutment		IS Angled Abutment
510(k) No.	K220517		K181138
Material	TI-6AL-4V ELI		TI-6AL-4V ELI
Design	 Hex Non-Hex		 Hex Non-Hex
Diameter(⌀)	5.3	6.3	4.5, 5.2, 5.7, 6.5
Length(mm)	7.5, 8.03	7.73, 8.37	7.0, 8.0
Angle (°)	15, 23		15, 25
Surface Treatment	Machine-		Tin Coating
Sterilization	End User Sterilization		End User Sterilization
SE Discussion	The subject device is similar in indications for Use, fundamental scientific technology, principle of operation, technology, functions, and materials with the identified reference device. The difference between the subject and reference device is the general design. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.		

<Magic Motion>

	Subject Device	**Reference Device**	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd.
Device Name	IBS System	CCM Abutment System	IBS Implant System II
Product Name	Magic Motion	UCLA Abutment	Magic motion
510(k) No.	K220517	K173120	K200753
Material	Ball Pin (TI-6AL-4V ELI) Body (Co-Cr-Mo Alloy)	POM(Poly Acetal) Co-Cr-Mo Alloy	Titanium Alloy (ASTM F 136)
Design			

Diameters (⌀)	4.0	4.0, 4.5, 5.0, 5.5	4.0
Total Length (mm)	10.61, 11.11, 11.56, 12.06, 12.11, 13.06, 13.11, 14.06, 14.11, 15.06	14.0, 15.0, 16.0, 17.0	10.05~16.05
Surface Treatment	Machine-	N/A	Machine-
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
SE Discussion	The subject device is similar in indications for Use, fundamental scientific technology, principle of operation, general design, technology, functions, and materials (Ball pin) with the identified reference device. The difference between the subject and reference device is the head(Ball Pin) shape changed to more round. This difference is to improve the connection of Magic Motion and Magic Motion Housing and doesn't impact product's substantial equivalence. And the Body materials changed Co-Cr-Mo Alloy. To support the materials, K173120 was added as a reference device. This difference is to improve strength doesn't affect device's fundamental functions and safety; therefore, it is substantial equivalent.		

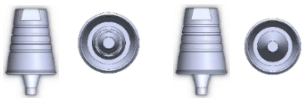
<Magic Motion Housing>

	Subject Device	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	IBS System	IBS Implant System II
Product Name	Magic Motion	Magic motion
510(k) No.	K220517	K200753
Material	TI-6AL-4V ELI	TI-6AL-4V ELI
Design		
Diameters (⌀)	5.16	5.3
Total Length (mm)	3.3	3
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 diameters and length. The height and diameter are changed from K200753 however, it doesn't impact product's safety and effectiveness. Therefore, it is substantially equivalent.	

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

	Subject Device	**Primary Predicate**	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	IBS System	Magicore System	Magicore System
Product Name	Magic Abutment	Magic Abutment	Magicore
510(k) No.	K220517	K212517	K152520
Material	TI-6AL-4V ELI	TI-6AL-4V ELI	TI-6AL-4V ELI
Design	 Hex Non-Hex	 Hex Non-Hex	
Diameters (⌀)	5.2, 5.7, 6.2, 6.7	5.2, 5.7, 6.2, 6.7	4.0, 4.5, 5.0, 5.5, 6.0, 6.5
Total Length(mm)	4.51, 5.51, 6.51, 7.51, 8.51	4.51, 5.51, 6.51, 7.51, 8.51	7.0 ~13.0
Surface Treatment	RBM(Blasting)	Machine-	RBM
Sterilization	End User Sterilization	End User Sterilization	Gamma Sterilization
SE Discussion	The subject device is same in fundamental scientific technology, technology, materials, dimensions, and design with the primary predicate. The difference between the subject and primary device is the surface treatment and sterilization. To support these discrepancies, K152520 was added as reference device. The surface treatment between the subject device and K152520 is exactly same. This surface change is intended to only improve scanning surface area and does not affect the actual equivalence of the product. Therefore, it is substantially equivalent.		

<Magic Abutment (Cement type _ Hex, Non-Hex)>

	Subject Device	**Primary Predicate**	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	IBS Implant System	Magicore System	Magicore System
Product Name	Magic Abutment	Magic Abutment	Magicore
510(k) No.	K220517	K212517	K152520
Material	TI-6AL-4V ELI	TI-6AL-4V ELI	TI-6AL-4V ELI
Design	 Hex Non-Hex	 Hex Non-Hex	
Diameters (⌀)	5.2, 5.7, 6.2, 6.7	5.2, 5.7, 6.2, 6.7	4.0, 4.5, 5.0, 5.5, 6.0, 6.5
Total Length(mm)	6.5, 7.5, 8.5, 9.5, 10.5	6.5, 7.5, 8.5, 9.5, 10.5	7.0 ~13.0
Surface Treatment	RBM(Blasting)	Machine-	RBM
Sterilization	End User Sterilization	End User Sterilization	Gamma Sterilization
SE Discussion	The subject device is same in fundamental scientific technology, technology, materials, dimensions, and design with the primary predicate. The difference between the subject and primary device is the surface treatment and sterilization. To support these discrepancies, K152520 was added as reference device. The surface treatment between the subject device and K152520 is exactly same. This surface change is intended to only improve scanning surface area and does not affect the actual equivalence of the product. Therefore, it is substantially equivalent.		

<Magic Multiunit Abutment(Cement type _ Hex, Non-Hex)>

	Subject Device	**Reference Device**	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	IBS Implant System	Magicore System	Magicore System
Product Name	Magic Multiunit Abutment	Magic Multiunit Abutment	Magicore
510(k) No.	K220517	K212517	K152520
Material	TI-6AL-4V ELI	TI-6AL-4V ELI	TI-6AL-4V ELI
Design	 Hex Non-Hex	 Hex Non-Hex	
Diameters (⌀)	4.8, 5.8	4.8, 5.8	4.0, 4.5, 5.0, 5.5, 6.0, 6.5
Angulation (°)	0, 5, 10, 15, 20, 25	0, 5, 10, 15, 20, 25	7.0 ~13.0
Surface Treatment	RBM(Blasting)	Machine-	RBM
Sterilization	End User Sterilization	End User Sterilization	Gamma Sterilization
SE Discussion	The subject device is same in fundamental scientific technology, technology, materials, dimensions and design with the primary predicate. The difference between the subject and primary device is the surface treatment and sterilization. To support these discrepancies, K152520 was added as reference device. The surface treatment between the subject device and K152520 is exactly same. This surface change is intended to only improve scanning surface area and does not affect the actual equivalence of the product. Therefore, it is substantially equivalent.		

<Magic Multiunit Cap>

	Subject Device	**Reference Device**	**Reference Device**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	IBS Implant System	Magicore System	Magicore System
Product Name	Magic Multiunit Cap	Magic Multiunit Cap	Magicore
510(k) No.	K220517	K212517	K152520
Material	TI-6AL-4V ELI	TI-6AL-4V ELI	TI-6AL-4V ELI
Design			
Diameters (⌀)	5.4, 6.4	5.4, 6.4	4.0, 4.5, 5.0, 5.5, 6.0, 6.5
Total Length (mm)	4.3	4.3	7.0 ~13.0
Surface Treatment	RBM(Blasting)	Machine-	RBM
Sterilization	End User Sterilization	End User Sterilization	Gamma Sterilization
SE Discussion	The subject device is same in fundamental scientific technology, technology, materials, dimensions and design with the primary predicate. The difference between the subject and primary device is the surface treatment. To support these discrepancies, K152520 was added as reference device. The surface treatment between the subject device and K152520 is exactly same. This surface change is intended to only improve scanning surface area and does not affect the actual equivalence of the product. Therefore, it is substantially equivalent.		

Non-Clinical Data:
Below tests were performed on the subject device:

- End User Sterilization Validation Test Report on Abutments made of Titanium ELI with RBM(Blasting) Surface treatment according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1
- Biocompatibility testing according to the ISO10993-1:2009, ISO 10993-5:2009, ISO 10993-6:2007, and ISO 10993-10:2010 on abutments made of Titanium ELI with RBM(Blasting) Surface treatment.

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

- 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 & K162099
- Biocompatibility testing according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-6:2007, and ISO 10993-10:2010 on abutments made of Titanium ELI referenced in K140806 & on Abutments made of CCM alloy referenced in K173120
- LAL information/testing per USP <85> as referenced in K162099
- Sterilization validation for devices on Fixtures according to ISO 11137-1 and ISO 11137-2
- Shelf Life Test Report on Fixture and Magicore Cap according to ASTM F1980
- End User Sterilization Validation Test Report on Abutments made of Titanium ELI 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 Testing according to ISO 14801:2016 referenced in K212517

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 K162099, surface roughness, surface composition analysis, and SEM imaging were provided, and it demonstrate the substantial equivalence.
The end user sterilization validation testing was performed on abutment made of Titanium ELI with RBM(Blasting) Surface treatment under the worst-case construction. This sterilization cycle has been validated by the overkill method to a sterility assurance level (SAL) of 10-6 according to ISO 17665-1 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
The biocompatibility testing was performed on abutments made of Titanium ELI with RBM(Blasting) Surface treatment according to the *ISO10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and it demonstrate the subject abutments are biocompatible.
Non-clinical tests followed the recommendations in the "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant abutments".

- 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 IBS 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, IBS System and its predicates are substantially equivalent.