September 23, 2020

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

Re: K202479
Trade/Device Name: IBS Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 28, 2020
Received: August 28, 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)*
K202479

Device Name
IBS Implant System

Indications for Use *(Describe)*
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 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.

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 Implant System
- Common Name: Endosseous dental implant
- Classification Name: Endosseous dental implant
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date prepared: 09/22/2020

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

Primary Predicate
K153350, IBS Implant System manufactured by InnoBioSurg Co., Ltd.

Reference Device
K113554, CMI Implant IS System by Neobiotech Co., Ltd.
K140806, IBS Implant System by InnoBioSurg Co., Ltd.
K150344, Dentis Dental Implant System by Dentis Co., Ltd.
K152520, Magicore System by InnoBioSurg Co., Ltd.
K162099, IBS Implant System II by InnoBioSurg Co., Ltd.
K172100, URIS OMNI System by TruAbutment Korea Co., Ltd.
K173120, CCM Abutment System by InnoBioSurg Co., Ltd.
K173141, CSM Submerged3-L Implant System by CSM Implant
K182448, Any Ridge Octa 1 System by MegeGen Implant Co., Ltd.
K192197, Magicore II System by InnoBioSurg Co., Ltd.

Indication for Use
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 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.

General Description

This submission is to add implants and abutments to the previously cleared device, IBS Implant System (K153350).
An endosseous dental implant is a device made of a material such as Ti-6AL-4V Eli (Conforming to ASTM Standard F-136). The IBS Implant System consists of dental implants, abutments, and screws for use in one or two-stage dental implant placement and restorations. The implant-abutment connection is tight and precise fitting with internal hex and Morse taper bevel.
The surface of the system has been treated with RBM (Resorbable Blasted media).

Below is Fixture dimension range:

Fixture	Diameters (Ø)	Length (mm)
NR Fix (Addition to K153350)	3.5	10, 11, 12, 13, 14 (Length of Surface treatment: 10, 12)
	3.8	10, 11, 12, 13, 14 (Length of Surface treatment: 10, 12)
Magic FC Mini (Newly Added)	3.55	9, 10, 11, 12, 13
Magic FC (Addition to K153350)	4	8, 10, 12, 14
	4.5	8, 10, 12, 14
	5	8, 10, 12, 14
	5.5	8, 10, 12, 14
	6	8, 10, 12, 14
	6.5	8, 10, 12, 14
Magic FC (Cutting Edge) (Addition to K153350)	4	8, 10, 12, 14
	4.5	8, 10, 12, 14
	5	8, 10, 12, 14
	5.5	8, 10, 12, 14
	6	8, 10, 12, 14
	6.5	8, 10, 12, 14

Below is abutment dimension range:

Abutments	Diameters (Ø)	Angle (°)	Length (mm)
Angled Abutment (Addition to K153350)	4.5	15	11.4, 12.4, 13.4, 14.4
		25	11.65, 12.65, 13.65, 14.65
	4.95	15	11.4, 12.4, 13.4, 14.4
		25	11.65, 12.65, 13.65, 14.65
Pair Abutment (Addition to K153350)	3.95, 4.5, 4.95, 5.5, 5.95, 6.5	0	Post Height: 4, 5.5, 6, 7, 7.5
Multiunit Abutment (Addition to K153350)	4.8	0, 17, 30	6.21, 6.76, 7.21, 7.76, 8.21, 8.76, 9.21, 9.76, 10.1, 10.21, 10.76, 11.1, 12.1, 13.1, 14.1
Multiunit Abutment Screw (Newly Added)	2.2	0	6.5
Multiunit Abutment Cap (Addition to K153350)	4.8	0	6
Temporary Abutment (Newly Added)	4.5	0	13.1

Multiunit Abutment Temporary Cylinder (Newly Added)	4.8	0	12
Multiunit Abutment Plastic Cylinder (Newly Added)	4.8	0	12
Multiunit Abutment CCM Cylinder (Newly Added)	4.8	0	12
Closing Screw (Newly Added)	3.0	0	4.8

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

Fixtures and abutments are packaged separately.
The Fixtures are supplied sterile. Fixtures are packaged with Closing screw.
The Angled Abutment, Pair Abutment, Multiunit Abutment, Multiunit Abutment Screw, Multiunit Abutment Cap, Temporary Abutment, Multiunit Abutment Temporary Cylinder, Multiunit Abutment Plastic Cylinder, and Multiunit Abutment CCM Cylinder are supplied non-sterile and should be sterilized before use.

The purpose of this submission is

- To add NR Fix ⌀3.5, 3.8 X 10, 11, 12, 13, 14mm of total length with length of surface treatment 10, 12mm.
- To add Magic FC Mini.
- To add Magic FC ⌀4, 4.5, 5, 5.5, 6, 6.5 X 8, 10, 12, 14mm.
- To add Magic FC (Cutting Edge) ⌀4, 4.5, 5, 5.5, 6, 6.5 X 8, 10, 12, 14mm.
- To change the product codes of the previously cleared NR Fix and Magic FC by adding "B" at the end of the product code.
- To change the product codes of the previously cleared Angled Abutment, Pair Abutment, and Multiunit Abutment by adding "B" at the end of the product codes.
- To add Angled Abutment ⌀4.5, 4.95 X 11.4, 11.65, 12.4, 12.65, 13.4, 13.65, 14.4, 14.65mm.
- To add Pair Abutment ⌀3.95, 4.5, 4.95, 5.5, 5.95, 6.5 X Post Heights 4, 5.5, 6, 7, 7.5mm.
- To add Multiunit Abutment ⌀4.8mm X 6.21, 6.76, 7.21, 7.76, 8.21, 8.76, 9.21, 9.76, 10.1, 10.21, 10.76, 11.1, 12.1, 13.1, 14.1mm.
- To add Multiunit Abutment Screw.
- To add Multiunit Abutment Cap ⌀4.8 X 6mm.
- To add Temporary Abutment.
- To add Multiunit Abutment Temporary Cylinder.
- To add Multiunit Abutment Plastic Cylinder.
- To add Multiunit Abutment CCM Cylinder.
- To add Closing Screw.

Materials:
Fixtures, Angled Abutment, Pair Abutment, Multiunit Abutment, Temporary Abutment and Multiunit Abutment Temporary Cylinder are fabricated from Ti-6AL-4V Eli (Conforming to ASTM Standard F-136).

Multiunit Abutment Plastic Cylinder is fabricated from Poly Diacetate. Multiunit Abutment CCM Cylinder is fabricated from Poly Diacetate, Co-Cr-Mo (Cobalt Chromium Molybdenum).

Summaries of Technology Characteristics:

1) Fixture

<NR Fix>

	Subject Device	**Primary Predicate**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	IBS Implant System	IBS Implant System
510(k) No.	N/A	K153350
Indications for use	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.	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.
Design	 Cutting Edge	 Cutting Edge
Material	Titanium Alloy (Ti-6Al-4V Eli) ASTM F136	Titanium Alloy (Ti-6Al-4V Eli) ASTM F136
Connection	Internal Hex, Submerged	Internal Hex, Submerged
Endosseous Implant	Tapered, Macro threads	Tapered, Macro threads
Diameters (Ø)	3.5, 3.8	3.5, 3.8
Lengths (mm)	10, 11, 12, 13, 14	9, 10, 11, 12, 13, 14, 15
D X L (Surface Tx L) (implants feature a non-blasted collar of 0, 1, and 2 mm lengths)	3.5 X 10 (10) 3.5 X 12 (12) 3.8 X 12 (10) 3.8 X 11 (10) 3.8 X 13 (12) 3.8 X 14 (12)	3.5 X 9 (9) 3.5 X 11 (11) 3.5 X 13 (13) 3.8 X 11 (9) 3.8 X 13 (11) 3.8 X 15 (13) 3.8 X 10 (9) 3.8 X 12 (11) 3.8 X 14 (13)

Modified Surface	RBM	RBM
Surgical Technique	1 stage and 2 stage, Self tapping	1 stage and 2 stage, Self tapping
Gamma Sterilization	Yes	Yes

Similarities

The NR Fix is substantially equivalent with the Primary predicate such as indications for Use, diameters, Length, surface treatment method, material, functions, general shape (Design), structure and applied production method.

Differences

The difference between the subject and predicate device is the length of the surface treatment. Compared to the predicate device, the subject's device's length of surface treatment is 10 and 12mm. Since the surface treatment length of subject device is included in range of primary predicate's surface treatment length, therefore, it doesn't impact product's substantial equivalence.

<Magic FC Mini>

	Subject Device	**Primary Predicate**	
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.	
Device Name	IBS Implant System	IBS Implant System	
510(k) No.	N/A	K153350	
Indications for use	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.	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.	
Design	 Magic FC Mini	 NR Fix	 Magic FC

	Non-Cutting Edge	Cutting Edge	Cutting Edge Non-Cutting Edge
Composition of Material	Titanium Alloy (Ti-6Al-4V Eli) ASTM F136	Titanium Alloy (Ti-6Al-4V Eli) ASTM F136	Titanium Alloy (Ti-6Al-4V Eli) ASTM F136
Connection	Internal Hex, Submerged	Internal Hex, Submerged	Internal Hex, Submerged
Endosseous Implant	Tapered, Macro threads	Tapered, Macro threads	Tapered, Macro threads
Diameters (⌀)	3.55	3.5, 3.8	4, 4.5, 5, 5.5, 6, 6.5
Lengths (mm)	9, 10, 11, 12, 13	9, 10, 11, 12, 13, 14, 15	7, 9, 11, 13, 15
Modified Surface	RBM	RBM	
Surgical Technique	1 stage and 2 stage, Self tapping	1 stage and 2 stage, Self tapping	
Gamma Sterilization	Yes	Yes	

Similarities

The Magic FC Mini is substantially equivalent with the Primary predicate such as indications for Use diameters, Length, surface treatment method, material, functions, general shape (Design), structure and applied production method.

Differences

Compared to the Primary predicate, the subject's device is non-cutting edge. This cutting-edge functions as self-tapping by creating a screw path. This difference doesn't impact product's substantial equivalence.

<Magic FC - Cutting Edge, Non-Cutting Edge >

	Subject Device	**Primary Predicate**
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	IBS Implant System	IBS Implant System
510(k) No.	N/A	K153350
Indications for use	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	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.	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.
Design		
	Cutting Edge, Non-Cutting Edge	Cutting Edge, Non-Cutting Edge
Composition of Material	Titanium Alloy (Ti-6Al-4V Eli) ASTM F136	Titanium Alloy (Ti-6Al-4V Eli) ASTM F136
Connection	Internal Hex Submerged	Internal Hex Submerged
Endosseous Implant	Tapered, Macro threads	Tapered, Macro threads
Diameters (⌀)	4, 4.5, 5, 5.5, 6, 6.5	4, 4.5, 5, 5.5, 6, 6.5
Lengths (mm)	8, 10, 12, 14	7, 9, 11, 13, 15
Modified Surface	RBM	RBM
Surgical Technique	1 stage and 2 stage, Self tapping	1 stage and 2 stage, Self tapping
Gamma Sterilization	Yes	Yes

Similarities

The Magic FC is substantially equivalent with the Primary predicate such as indications for Use diameters, Length, surface treatment method, material, functions, general shape (Design), structure and applied production method.

Differences

Compared to the Primary predicate, the subject's device's length is different. However, the lengths of subject device are included in range of primary predicate's lengths. Therefore, it doesn't impact product's substantial equivalence.

2) Abutments

<Angled Abutment>

	Subject Device	**Primary Predicate**
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd.
Device Name	IBS Implant System	IBS Implant System
510(k) No.	N/A	K153350
Composition of Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Design		
Diameters (⌀)	4.5, 4.95	4, 4.5, 5
Length (mm)	11.4, 11.65, 12.4, 12.65, 13.4, 13.65, 14.4, 14.65	10.6, 10.85, 11.4, 11.65, 12.4, 12.65, 13.4, 13.65, 14.4, 14.65
Angle (°)	15, 25	15, 25, 30
Surface treatment	Machine	Machine
Sterilization	End User Sterilization	End User Sterilization

Similarities

The Angled Abutment is substantially equivalent with the Primary predicate such as diameters, Length, intended use, material, functions, general shape (Design), structure, angulation and applied production method.

Differences

Compared to the Primary predicate, the diameters and lengths of subject device are different; however, the subject device's dimensions are included in range of primary predicate's. Therefore, it doesn't impact product's substantial equivalence.

<Pair Abutment>

	Subject Device	**Primary Predicate**	**Reference Predicate**
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	IBS Implant System	IBS Implant System	IBS Implant System
510(k) No.	N/A	K153350	K140806
Composition of Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Design			
		Non-hex	Hex
Diameters (⌀)	3.95, 4.5, 4.95, 5.5, 5.95, 6.5	3.5, 4, 4.5, 5, 5.5, 6, 6.5	4, 4.5, 5, 5.5, 6, 6.5
Post Heights (mm)	4, 5.5, 6, 7, 7.5	6	4, 6, 7.5
Surface treatment	Machine	Machine	Machine
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization

Similarities

The Pair Abutment is substantially equivalent with the primary predicate device such as indications for use, fundamental scientific technology, principle of operation, general shape (design), functions, dimensions, surface treatment and materials.

Differences

Compared to the Primary predicate device 4, 5.5, 7, 7.5mm post heights are added to the new subject system. K140806 was chosen to support the range of the subject device dimension. Therefore, it doesn't impact product's substantial equivalence.

<Multiunit Abutment>

	Subject Device	**Primary Predicate**	**Reference Predicate**
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd.	Dentis Co., Ltd.
Device Name	IBS Implant System	IBS Implant System	Denis Dental Implant System
510(k) No.	N/A	K153350	K150344
Composition of Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Design			
Diameters (⌀)	4.8	3.6, 4, 4.5, 5, 5.5, 6	4.8
Length (mm)	6.21, 6.76, 7.21, 7.76, 8.21, 8.76, 9.21, 9.76, 10.1, 10.21, 10.76, 11.1, 12.1, 13.1, 14.1	9, 11, 13, 16	6.08, 6.69, 8.08, 8.69
Angle (°)	0, 17, 30	0, 17, 30	17, 30
Surface treatment	Machine	Machine	Machine
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization

Similarities

The Multiunit Abutment is substantially equivalent with the Primary predicate such as intended use, material, functions, general shape (Design), structure, angulation and applied production method.

Differences

Compared to the primary predicate, the subject multiunit abutment has more various lengths. The Reference Predicate MU Angled Abutment (K150344), supports substantial equivalence of the subject device's 4.8 diameter and 6.21, 6.76, 7.21, 7.76, 8.21 lengths. The Primary Predicate Multiunit Abutment (K153350), support rest lengths of the subject device. This difference of range does not raise an issue in performance or safety.

<Multiunit Abutment Screw>

	Subject Device	**Reference Predicate**	
Manufacturer	InnoBioSurg Co., Ltd	Dentis Co., Ltd.	InnoBioSurg Co., Ltd
Device Name	IBS Implant System	Dentis Dental Implant System	IBS Implant System
510(k) No.	N/A	K150344	K140806
Composition of Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Design			
Head Diameters (⌀)	2.2	1.98	2.5
Length (mm)	6.5	3.7	7.6
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
Principle of operation	Abutment screw is used for securing the abutment to the endosseous implant.	Abutment screw is used for securing the abutment to the endosseous implant.	Abutment screw is used for securing the abutment to the endosseous implant.

Similarities

The Multiunit Abutment Screw is substantially equivalent in intended use, general shape, material, Sterilization and Principle of operation as the predicates.

Differences

K150344 and K140806 were added as reference device to support the substantial equivalence of dimensions differences. Although the reference device's dimensions are not exactly same as the subject device, it does not cause a matter in substantial equivalence since the size difference is very minor. The reduced diameter is in the screw head, not the threaded retention area which could potentially affect mechanical performance. Therefore, the difference doesn't impact product's substantial equivalence and no additional fatigue testing was necessary.

<Multiunit Abutment Cap>

	Subject Device	**Primary Predicate**	**Reference Predicate**
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd.	Neobiotech Co., Ltd.
Device Name	IBS Implant System	IBS Implant System	CMI Implant IS System
510(k) No.	N/A	K153350	K113554
Composition of Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli	POM
Design			
Diameters (⌀)	4.8	4.95, 5.35, 5.85, 6.35, 6.85, 7.35	4.5, 5.2, 5.7, 6.5
Length (mm)	6	4.95, 6.75, 8.8, 11.9	4.5, 5.5, 6, 7, 8
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization

Similarities

The Multiunit Abutment Cap is substantially equivalent in intended use, fundamental scientific technology, principle of operation, design, functions, materials as the identified predicates.

Differences

Compared to the Primary predicate device, the diameter and length range of the subject device are different. K113554 was added to support this discrepancy. Therefore, the difference doesn't impact product's substantial equivalence.

<Temporary Abutment>

	Subject Device	**Reference Predicate**	
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd.	CSM Implant
Device Name	IBS Implant System	CCM Abutment System	CSM Submerged3-L Implant System
510(k) No.	N/A	K173120	K173141
Composition of Material	Ti-6Al-4V Eli	Poly Diacetate, Co-Cr-Mo	Ti-6Al-4V Eli
Design			
Diameters (⌀)	4.5	4, 4.5, 5, 5.5, 6	4.5, 5.5
Length (mm)	13.1	14, 15, 16, 17	12.8, 13.3, 13.8, 14.8, 15.8, 16.8
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization

Similarities

The Temporary Abutment is substantially equivalent in intended use, fundamental scientific technology, principle of operation, design, functions, and materials as the identified predicates.

Differences

Compared to the predicate devices, the dimensions and design are slightly different. However, the subject device dimensions are in range of the predicate's and the design difference doesn't change product fundamental characteristics and application. Therefore, the differences do not impact product's substantial equivalence.

<Multiunit Abutment Temporary Cylinder>

	Subject Device	**Reference Predicate**
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd
Device Name	IBS Implant System	IBS Implant System II
510(k) No.	N/A	K162099
Composition of Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Design		
Diameters (⌀)	4.8	3.5, 4, 4.5, 5, 5.5, 6
Length (mm)	12	12
Sterilization	End User Sterilization	End User Sterilization

Similarities

The Multiunit Abutment Temporary Cylinder is substantially equivalent in intended use, fundamental scientific technology, principle of operation, design, functions and materials as the identified predicate.

Differences

Compared to the predicate device, the diameter is different, however, the diameter of the subject device is in range of the reference device's. Therefore, the difference doesn't impact product's substantial equivalence.

<Multiunit Abutment Plastic Cylinder>

	Subject Device	**Reference Predicate**
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd
Device Name	IBS Implant System	IBS Implant System II
510(k) No.	N/A	K162099
Composition of Material	Poly Diacetate	Poly Diacetate
Design		
Diameters (⌀)	4.8	3.5, 4, 4.5, 5, 5.5, 6
Length (mm)	12	12
Sterilization	End User Sterilization	End User Sterilization

Similarities

The Multiunit Abutment Plastic Cylinder is substantially equivalent in intended use, fundamental scientific technology, principle of operation, design, functions and materials as the identified predicate.

Differences

Compared to the predicate device, the diameter is different, however, the diameter of the subject device is in range of the reference device's. Therefore, the difference doesn't impact product's substantial equivalence.

<Multiunit Abutment CCM Cylinder>

	Subject Device	Reference Predicate
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd
Device Name	IBS Implant System	IBS Implant System II
510(k) No.	N/A	K162099
Composition of Material	Poly Diacetate, Co-Cr-Mo	Ti-6Al-4V Eli
Design		
Diameters (⌀)	4.8	3.5, 4, 4.5, 5, 5.5, 6
Length (mm)	12	12
Sterilization	End User Sterilization	End User Sterilization

Similarities

The Multiunit Abutment CCM Cylinder is substantially equivalent in intended use, fundamental scientific technology, principle of operation, design, functions and materials as the identified predicate.

Differences

Compared to the predicate device, the diameter is different, however, the diameter of the subject device is in range of the reference device's. Therefore, the difference doesn't impact product's substantial equivalence.

<Closing Screw>

	Subject Device	**Primary Predicate**
Manufacturer	InnoBioSurg Co., Ltd	InnoBioSurg Co., Ltd
Device Name	IBS Implant System	IBS Implant System
510(k) No.	N/A	K140806
Composition of Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Design		
Diameters (⌀)	3.0	3.4
Length (mm)	4.8	5.65
Sterilization	Gamma Sterilization	Gamma Sterilization

Similarities

The Closing Screw has substantially equivalent in intended use, fundamental scientific technology, principle of operation, functions and materials as the identified predicate.

Differences

Compared to the predicate device the dimension is different. Although the reference device's dimensions are not exactly same as the subject device, it does not cause a matter in substantial equivalence since the size difference is very minor. Therefore, the difference doesn't impact product's substantial equivalence.

Non-Clinical Data:

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

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

- Sterilization validation for devices provided sterile per ISO 11137-1 and ISO 11137-2 referenced in K153350
- LAL information/testing per USP <85> as referenced in K162099
- Shelf Life Test on Fixtures 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, ISO 10993-6:2007, and ISO 10993-10:2010 on abutments referenced in K140806 and K173120
- 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 Testing according to ISO 14801 referenced in K153350

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, K153350, surface roughness, surface composition analysis, and SEM imaging were provided and it demonstrate the substantial equivalence.
The fatigue testing per ISO 14801 was not conducted as the predicate device remains as worst-case based on the dimensional worst-case analysis.
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 IBS Implant 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 Implant System and its predicates are substantially equivalent.