



March 16, 2018

InnoBioSurg Co., Ltd.
April Lee
Consultant
Withus Group Inc.
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K173120
Trade/Device Name: CCM Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 14, 2018
Received: February 14, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173120

Device Name

CCM Abutment System

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter

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Device Information

- Trade Name: CCM Abutment System
- Common Name: Dental Abutment System
- Classification Name: Endosseous dental implant abutment
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date prepared: 03/16/2018

Primary Predicate

K153350, IBS Implant System by Innobiosurg Co., Ltd.

Reference Predicates

- K140806, IBS Implant System by Innobiosurg Co., Ltd
- K162099, IBS Implant System II by Innobiosurg Co., Ltd.
- K161244, s-Clean OneQ-SL Narrow Implant System by Dentis Co., Ltd.

Device Description

CCM Abutment System is used with a dental implant to provide support to prosthetic restorations such as crown, bridge and overdentures in partially or fully edentulous patients. CCM Abutment System consists of UCLA Abutment and titanium abutment screws. All subject abutments are intended to be cast at zero angulations and placed on dental implant bodies which do not require angle correction.

UCLA Abutment

UCLA Abutments are pre-manufactured prosthetic abutments directly connected to the endosseous dental implant intended for permanent restoration, for either single or multiple tooth screw retained restorations. The lower part of the abutment which connects directly to the implant is made of Co-Cr-Mo alloy, and the upper part is made of plastic (Poly Diacetate). The plastic part is dissolved once the casting is done. The abutment screw is connected to the implant by a prosthetic screw, supplied with the abutment, and made of Ti-6AL-4V Eli. UCLA Abutments are intended for no angulation and straight implantation only. The abutments are supplied non-sterile, to be steam sterilized by the user according to the labeling, and intended for single use.

Multi-unit CCM Cylinder

Multi-unit CCM 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.

The subject device is compatible with the following Implants:

K number	Compatible Implants
K140806	IBS Implant system
K152520	MagiCore System
K153350	IBS Implant System

The CCM Abutment system is provided non-sterile and packaged separately. The abutments should be sterilized before use. Abutment screw (OIAS400) was cleared from K140806.

The UCLA abutments, Burn out core cylinder and cap are not intended to be cast at angulation or placed to provide angular correction. Plastic sleeve of UCLA Abutment can replace the Non-precious metal (Co-Cr Alloy). All finished devices are final abutments.

The diameters and lengths of the CCM Abutment System are below:

1) UCLA Abutment

The gingival height could be 1-4mm, angulation straight only, length of abutment post of 4-10mm.

Assembled torque: 30N·cm

No	Diameter (Ø)	Cuff	Length	Remark
1	4 mm	1 mm	14 mm	Hex/Non-Hex
2		2 mm	15 mm	
3		3 mm	16 mm	
4		4 mm	17 mm	
5	4.5 mm	1 mm	14 mm	
6		2 mm	15 mm	
7		3 mm	16 mm	
8		4 mm	17 mm	
9	5 mm	1 mm	14 mm	
10		2 mm	15 mm	
11		3 mm	16 mm	
12		4 mm	17 mm	
13	5.5 mm	1 mm	14 mm	
14		2 mm	15 mm	
15		3 mm	16 mm	
16		4 mm	17 mm	

2) Burn out core cylinder (Screw type)

No Angulation straight only, length of abutment post of 4-9mm.

Assembled torque: 30N·cm

No	Diameter (Ø)	Length	Remark
1	5 mm	8.5 mm	Hex/Non-Hex
2	6 mm	8.65 mm	

3) Burn out core cap (Cemented type)

No Angulation straight only, length of abutment post of 4-9mm.

Assembled torque: 30N·cm

No	Diameter (Ø)	Length	Remark
1	5 mm	9.15 mm	Hex/Non-Hex
2	6 mm	9.15 mm	

4) Burn out core T cylinder (Screw type)

No Angulation straight only, length of abutment post of 4-9mm.

Assembled torque: 30N·cm

No	Diameter (Ø)	Length	Remark
1	5 mm	10.65 mm	Hex/Non-Hex
2	6 mm	10.8 mm	

5) Burn out core U cylinder (Screw type)

No Angulation straight only, length of abutment post of 4-9mm.

Assembled torque: 30N·cm

No	Diameter (Ø)	Length	Remark
1	5 mm	12.25 mm	Hex/Non-Hex
2	6 mm	12.4 mm	

6) Burn out core U cap (Cemented type)

No Angulation straight only, length of abutment post of 4-9mm.

Assembled torque: 30N·cm

No	Diameter (Ø)	Length	Remark
1	5 mm	12.95 mm	Hex/Non-Hex
2	6 mm	12.95 mm	

7) Multi-unit CCM Cylinder

No Angulation straight only, length of abutment post of 4-9mm.

Assembled torque: 30N·cm

No	Diameter (Ø)	Length	Remark
1	4.8 mm	12 mm	Hex/Non-Hex

Indication for Use

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.

Non-Clinical Data:

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Biocompatibility tests according to ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-10:2010 and ISO 10993-11:2006.
- Galvanic Reaction Test between CoCr alloy and non-precious metal

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

- End User Steam Sterilization Test according to ISO 17665-1:2006, -2:2009 and ANSI/AAMI ST79 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.

Biocompatibility Test was conducted for the subject devices and it demonstrates that the subject device is biocompatible and substantial equivalence with the predicate device, K161244.

The galvanic reaction testing between the CoCr alloy and non-precious dental alloys, Ti Gr.5. was performed for subject device and compatible implants. As the FDA guidance of “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant abutments”, corrosion potential of each CoCr alloy and Ti Gr.5 and couple potential for assembled CoCr alloy and Ti Gr.5 were assessed.

The end user sterilization test was performed for predicate device, K140806 and leveraged for the subject device because the product category, material, manufacturing process, facility, and packaging is the exactly the same as the predicate, K140806.

The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Comparison to Predicate Devices:

UCLA Abutment			
Device Name	Subject device	Primary Predicate device	Reference Predicate device
	CCM Abutment System	IBS Implant system	s-Clean OneQ-SL Narrow Implant System
510k	N/A	K153350	K161244
Part Name	UCLA Abutment (Hex, Non-Hex)	UCLA Abutment	S-clean CCM Abutment (Narrow)
Material	Co-Cr-Mo Alloy Poly Diacetate	Titanium Alloy Poly Diacetate	Co-Cr-Mo Alloy
Manufacturer	Innobiosurg Co.,Ltd	Innobiosurg Co.,Ltd	Dentis Co.,Ltd
Indications for use	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 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. This system is intended for delayed loading.	The s-Clean One-Q-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.
Dimension	Ø 4mm, Ø 4.5mm, Ø 5mm, Ø 5.5mm (D) X 14,15,16,17 mm (L)	Ø3.5mm, Ø4mm, Ø4.5mm, Ø5mm, Ø5.5mm (D) X 14,15,16,17 mm (L)	Ø 4.0 mm (D) x 14.5 and 15 mm (L)

Restoration angulations	No Angle	No Angle	No Angle
Design			
Principle of Operation	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis

Burn out core cylinder (Hex and Non-Hex)			
Device Name	Subject device	Primary Predicate device	Reference Predicate device
	CCM Abutment System	IBS Implant system	s-Clean OneQ-SL Narrow Implant System
510k	N/A	K153350	K161244
Part Name	Burn out core cylinder	UCLA Abutment	S-clean CCM Abutment (Narrow)
Material	Co-Cr-Mo Alloy Poly Diacetate	Titanium Alloy Poly Diacetate	Co-Cr-Mo Alloy
Manufacturer	Innobiosurg Co.,Ltd	Innobiosurg Co.,Ltd	Dentis Co.,Ltd
Indications for use	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	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	The s-Clean One-Q-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

	procedures. This system is intended for delayed loading.	stage surgical procedures. This system is intended for delayed loading.	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.
Principle of Operation	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis
Hex			
Dimension	Ø 5mm, Ø 6mm (D) X 8.5, 8.65 mm (L)	Ø3.5mm, Ø4mm, Ø4.5mm, Ø5mm, Ø5.5mm (D) X 14,15,16,17 mm (L)	Ø 4.0 mm (D) x 14.5 and 15 mm (L)
Restoration angulations	No Angle	No Angle	No Angle
Design			
Non-Hex			
Dimension	Ø 5mm, Ø 6mm (D) X 8.5, 8.65 mm (L)	Ø3.5mm, Ø4mm, Ø4.5mm, Ø5mm, Ø5.5mm (D) X 14,15,16,17 mm (L)	Ø 4.0 mm (D) x 14.5 and 15 mm (L)
Restoration angulations	No Angle	No Angle	No Angle
Design			

Burn out core cap			
Device Name	Subject device	Primary Predicate device	Reference Predicate device
	CCM Abutment System	IBS Implant system	s-Clean OneQ-SL Narrow Implant System
510k	N/A	K153350	K161244
Part Name	Burn out core cap	UCLA Abutment	S-clean CCM Abutment (Narrow)
Material	Co-Cr-Mo Alloy Poly Diacetate	Titanium Alloy Poly Diacetate	Co-Cr-Mo Alloy
Manufacturer	Innobiosurg Co.,Ltd	Innobiosurg Co.,Ltd	Dentis Co.,Ltd
Indications for use	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 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. This system is intended for delayed loading.	The s-Clean One-Q-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.
Principle of Operation	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis
Hex			

Dimension	Ø 5mm, Ø 6mm (D) X 9.15 mm (L)	Ø3.5mm, Ø4mm, Ø4.5mm, Ø5mm, Ø5.5mm (D) X 14,15,16,17 mm (L)	Ø 4.0 mm (D) x 14.5 and 15 mm (L)
Restoration angulations	No Angle	No Angle	No Angle
Design			
Non-Hex			
Dimension	Ø 5mm, Ø 6mm (D) X 9.15 mm (L)	Ø3.5mm, Ø4mm, Ø4.5mm, Ø5mm, Ø5.5mm (D) X 14,15,16,17 mm (L)	Ø 4.0 mm (D) x 14.5 and 15 mm (L)
Restoration angulations	No Angle	No Angle	No Angle
Design			

Burn out core T Cylinder			
Device Name	Subject device	Primary Predicate device	Reference Predicate device
	CCM Abutment System	IBS Implant system	s-Clean OneQ-SL Narrow Implant System
510k	N/A	K153350	K161244
Part Name	Burn out core T cylinder	UCLA Abutment	S-clean CCM Abutment (Narrow)
Material	Co-Cr-Mo Alloy Poly Diacetate	Titanium Alloy Poly Diacetate	Co-Cr-Mo Alloy
Manufacturer	Innobiosurg Co.,Ltd	Innobiosurg Co.,Ltd	Dentis Co.,Ltd

Indications for use	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 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. This system is intended for delayed loading.	The s-Clean One-Q-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.
Principle of Operation	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis
Hex			
Dimension	Ø 5mm, Ø 6mm (D) X 10.65, 10.8 mm (L)	Ø3.5mm, Ø4mm, Ø4.5mm, Ø5mm, Ø5.5mm (D) X 14,15,16,17 mm (L)	Ø 4.0 mm (D) x 14.5 and 15 mm (L)
Restoration angulations	No Angle	No Angle	No Angle
Design			
Non-Hex			
Dimension	Ø 5mm, Ø 6mm (D) X 10.65, 10.8 mm (L)	Ø3.5mm, Ø4mm, Ø4.5mm, Ø5mm, Ø5.5mm (D) X 14,15,16,17 mm (L)	Ø 4.0 mm (D) x 14.5 and 15 mm (L)

Restoration angulations	No Angle	No Angle	No Angle
Design			

Burn out core U Cap				
	Subject device	Primary Predicate device	Reference Predicate device	Reference Predicate device
510k	N/A	K153350	K162099	K161244
Device Name	CCM Abutment System	-	IBS Implant system II	s-Clean OneQ-SL Narrow Implant System
Part Name	Burn Out Core U Cap (Hex)	-	Multiunit Ti Cylinder	S-clean CCM Abutment (Narrow)
Material	Co-Cr-Mo Alloy Poly Diacetate	-	Titanium Alloy	Co-Cr-Mo Alloy
Manufacturer	Innobiosurg Co.,Ltd	Innobiosurg Co.,Ltd	Innobiosurg Co.,Ltd	Dentis Co.,Ltd
Indications for use	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	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. This	Intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement-retained, screw- retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for	The s-Clean One-Q-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

	system is intended for delayed loading.	system is intended for delayed loading.	delayed loading.	mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.
Principle of Operation	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis	a screw retained restoration type of abutment using a screw to fix a prosthesis	
Hex				
Dimension	Ø5mm (D) X 12.95 mm (L)	-	Ø3.5mm, Ø4mm, Ø4.5mm, Ø5mm, Ø5.5mm X 12 mm (L)	Ø 4.0 mm (D) x 14.5 and 15 mm (L)
Restoration angulations	No Angle	-	No Angle	No Angle
Design		-		
Non-Hex				
Dimension	Ø5mm (D) X 12.95 mm (L)	-	Ø3.5mm, Ø4mm, Ø4.5mm, Ø5mm, Ø5.5mm X 12 mm (L)	Ø 4.0 mm (D) x 14.5 and 15 mm (L)
Restoration angulations	No Angle	-	No Angle	No Angle
Design		-		

Multi-unit CCM Cylinder				
	Subject device	Primary Predicate device	Reference Predicate device	Reference Predicate device
510k	NA	K153350	K162099	K161244
Part Name	Multi-unit CCM Cylinder (Hex, Non-Hex)	-	Multiunit Ti Cylinder	MU CCM Cylinder
Material	Co-Cr-Mo Alloy Poly Diacetate	-	Titanium Alloy	Co-Cr-Mo Alloy
Manufacturer	Innobiosurg Co.,Ltd	Innobiosurg Co.,Ltd	Innobiosurg Co.,Ltd	Dentis Co.,Ltd
Indications for use	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 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. This system is intended for delayed loading.	Intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement-retained, screw- retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading.	The s-Clean One-Q-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.
Dimension	Ø 4.8 mm x 12 mm (L)	-	Ø3.5mm, Ø4mm, Ø4.5mm, Ø5mm, Ø5.5mm, Ø6mm x 12 mm (L)	Ø 4.8 mm (D) x 14.25 mm (L)

Restoration angulations	No Angle	-	No Angle	No Angle
Design		-		

Abutment Screw			
	Subject device	Primary Predicate device	Reference Predicate device
510k	NA	K153350	K140806
Device Name	CCM Abutment System	-	IBS Implant System
Part Name	Abutment Screw	-	Abutment Screw
Material	Titanium Alloy		Titanium Alloy
Manufacturer	Innobiosurg Co.,Ltd	Innobiosurg Co.,Ltd	Innobiosurg Co.,Ltd
Indications for Use	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 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. 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 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.
design		-	
Diameter	ø 2	-	ø 2.5
Length	7mm	-	7.6mm
Material	identical	-	Titanium Alloy (ASTM F 136)

Substantial Equivalence Discussion

Similarities:

The subject device has identical material, machining, manufacturing process, angulation and indication for use and similar design, dimension and technological characteristics as the predicate devices.

The subject device has been supposed to performance and product validations prior to release. Testing including biocompatibility tests has been performed to ensure the devices comply with the applicable International and US FDA Guidance.

Differences:

The differences between the subject device and the primary predicate are:

1) Material

The subject device is made of CCM alloy but the primary predicate is made of Titanium Alloy. To support this discrepancy, the predicate, K161244 is selected as reference and biocompatibility testing were performed on the subject device.

2) Slight differences in abutment designs

The subject device and predicate devices are detailed shape and dimension of each abutment. To support this discrepancy, we chose our own predicates, K140806, K153350, and K162099.

Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicates and do not raise different questions of safety and effectiveness than the predicate.

Conclusion

The CCM Abutment 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, CCM Abutment System and its predicates are substantially equivalent.