January 7, 2022

Cybermed Inc.
Cheol Young Kim
President
6-26, Yuseong-daero 1205 beon-gil
Yuseong-gu, Daejeon 34104
REPUBLIC OF KOREA

Re: K210039
Trade/Device Name: CORE1 Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 29, 2021
Received: December 6, 2021

Dear Cheol Young Kim:

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
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)*
K210039

Device Name
CORE1 Implant system

Indications for Use *(Describe)*
CORE1 Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.

CORE1 Implant System 3.3mm diameter implants may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.

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)

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510(k) Summary

Date: January 7, 2022

I. SUBMITTER

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Tel: +82-42-716-3070

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II. DEVICE INFORMATION

·Device's Trade name: CORE1 Implant System

·Classification Name: implant, endosseous, root-form

·Device's Common Name: Endosseous dental implant

·Regulation Number 872.3640

·Class: 2

·Primary Product Code: DZE

·Secondary Product Code: NHA

III. PREDICATE DEVICE

Primary predicate device

K153639, OneQ-SL s-Clean Implant System, Dentis Co., Ltd.

Reference device

K161244, s-Clean OneQ-SL Narrow Implant System, Dentis Co., Ltd.

K190837, Internal Hex Implant System, EBI Inc.

K123988, Xpeed AnyRidge Internal Implant System, MegaGen Implant Co., Ltd

K172100, URIS OMNI System, Tru Abutment Inc.

K161689, OSSTEM Implant System – Abutment, OSSTEM Implant Co., Ltd.

K140507, Hiossen Prosthetic System, OSSTEM Implant Co., Ltd.

K173570, SD Abutment, Surgident Co., Ltd.

K173141, CSM Submerged3-L Implant System, CSM Implant

K181138, IS-III active System, Neobiotech. Co., Ltd.

K072642, BIOMET 3i Dental Abutments & Restorative Components, BIOMET 3i, Inc.

K153521, IH Implant System, Sewon Medix Inc.

K120847, ET/SS Implant System, OSSTEM Implant Co., Ltd.

IV. DEVICE DESCRIPTION

1) CORE1 Fixture

CORE1 Fixture is a thread type implant made of CP Titanium Gr.4 according to ASTM F67 which will be placed in the alveolar bone to replace the function of missing tooth. This device has connection between the upper prosthesis and the internal hex. Fixture's surface is treated with SLA (Sandblasted with Large-grit and Acid-etching). It is only part to be implanted into bone, and to provide connection of prosthetic device or other components of a dental implant set with human body (mandibular or maxillary bone). Fixtures are provided after gamma sterilization as a set package including a cover screw or as a single fixture.

2) CORE1 Abutment

- CORE1 Abutment intended for Single Unit restorations is a superstructure of a dental implant system and connecting elements between the dental implant and the crown. It is to made of Ti-6Al-4V ELI (ASTM F136), and intended to be placed on the fixture allows single prosthetic restorations to restore a patient's chewing function. Abutment Screw made of Ti-6Al-ELI (ASTM F136) is used to connect and fix the abutment to the fixture. The contained various abutments and accessories in the system are Solid Abutment, Cement Abutment, Angled Abutment, Milling Abutment, Temporary Abutment, Solid Protect Cap, Cover Screw, Healing Abutment, Healing Abutment (Scan). Angled Abutment can select 15° and 25° angles for prosthetics, and Milling Abutment is up to 20° for hand milling only.

- CORE1 Abutment intended for Multi-Unit restorations is a superstructure of a dental implant system and connecting elements between the dental implant and the bridge. It is to made of Ti-6Al-4V ELI (ASTM F136), and intended to be placed on the fixture allows multi prosthetic restorations to restore a patient's chewing function. Universal Plastic Cylinder is a burn-out device only used in the lab for casting and is not part of the final restoration. Abutment Screw made of Ti-6Al-ELI (ASTM F136) is used to connect and fix the abutment to the fixture. The contained various abutments and accessories in the system are Universal Abutment, Universal Angled Abutment, Universal Ti Cylinder, Universal Temporary Cylinder, Universal Healing Cap. Universal Angled Abutment has angles of 17°/30°.

V. INDICATION FOR USE

CORE1 Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.

CORE1 Implant System 3.3mm diameter implants may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.

VI. COMPARISON OF TECHNILOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1 : Substantial Equivalence – Indication for Use Statements

EQUIVALENCE DISCUSSION	**Subject device** K210039 COE1 Implant System Cybermed Inc.	**Predicate device** K153639 OneQ-SL s-Clean Implant System DENTIS CO., LTD.	**Reference device** K161244 s-Clean OneQ-SL Narrow Implant System Dentis Co., Ltd.
Indications for Use Statement	CORE1 Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading. CORE1 Implant System 3.3mm diameter implants may be used as an artificial root structure for single tooth replacement of	The OneQ-SL s-Clean Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; Cemented 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. This system is intended for delayed 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

	mandibular central and lateral incisors and maxillary lateral incisors.		has been achieved and with appropriate occlusal loading.

This language is identical and substantially equivalent to the identified primary predicate, OneQ-SL s-Clean Implant System, Dentis Co., Ltd. K153639. To support the smaller platform diameter Ø 3.3mm, s-Clean OneQ-SL Narrow Implant System K161244 was added as reference device. The differences in language with reference K161244 related to immediate loading does not apply to the Core1 Implant System, as the Core1 Implant System is intended only for delayed loading.

Table 2 : Substantial Equivalence EQUIVALENCE DISCUSSION – Technological characteristics – Implant

	Subject Device	**Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**	**EQUIVALENCE DISCUSSION**
Part Name	CORE1 Fixture	OneQ-SL s-Clean Fixture	s-Clean OneQ-SL Narrow Implant	BLT II OS Implant	XPEED AnyRidge Internal Fixture	
Trade Name	CORE1 Implant System	OneQ-SL s-Clean Implant System	s-Clean OneQ-SL Narrow Implant System	Internal Hex Implant System	XPEED AnyRidge Internal Implant System	
Manufacturer	Cybermed Inc.	DENTIS CO., LTD.	Dentis Co., Ltd.	EBI Inc.	MegaGen Implant Co., Ltd	
510(k) Number	K210039	K153639	K161244	K190837	K123988	
Material	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	Ti-6Al-4V ELI (ASTM F136)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	**Equivalent** Compared to the predicate and reference device, the

						subject device's raw material is same as predicate device.
Surface treatment	SLA	SLA	SLA	SLA	SLA	**Same**
Connection type	Internal Hex	Internal Hex	Internal Hex	Internal Hex	Internal Hex	**Same**
Diameter (Ø) & Total Length (mm)	Ø 3.3 x 8.5, 10.0, 11.5, 13.0mm Ø 3.6 x 8.5, 10.0, 11.5, 13.0 mm Ø 3.8 x 8.5, 10.0, 11.5, 13.0 mm Ø 3.82 x 8.5, 10.0, 11.5, 13.0 mm Ø 4.1 x 7.0, 8.5, 10.0, 11.5, 13.0 mm Ø 4.2 x 7.0, 8.5, 10.0, 11.5, 13.0 mm Ø 4.35 x 7.0, 8.5, 10.0, 11.5, 13.0 mm Ø 4.6 x 7.0, 8.5, 10.0, 11.5, 13.0 mm Ø 4.65 x 7.0, 8.5, 10.0, 11.5, 13.0 mm Ø 4.97 x 7.0, 8.5, 10.0, 11.5, 13.0 mm	Ø 3.5 x 7.0, 8.0, 10.0, 12.0, 14.0mm Ø 3.6 x 7.0, 8.0, 10.0, 12.0, 14.0mm Ø 3.7 x 7.0, 8.0, 10.0, 12.0, 14.0mm Ø 4.2 x 7.0, 8.0, 10.0, 12.0, 14.0mm Ø 4.7 x 7.0, 8.0, 10.0, 12.0, 14.0mm Ø 5.8 x 7.0, 8.0, 10.0, 12.0mm Ø 6.8 x 7.0, 8.0, 10.0, 12.0mm	Ø 3.0 x 10.0, 12.0, 14.0mm Ø 3.3 x 10.0, 12.0, 14.0mm	Ø 3.25-5.5 x 7-18mm	Ø 3.9 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 4.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 4.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 5.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 5.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 6.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 6.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 7.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 7.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm Ø 8.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm	**Equivalent** The combined diameter and total length of subject device is slightly different with predicate and reference device, but all the subject combination of diameter and length is within the range of dimension. Subject device verified through performance test, so this difference of range doesn't impact substantial equivalence.
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterile	Gamma Sterilization	**Same**
Implant Type	Bone Level	Bone Level	Bone Level	Bone Level	Bone Level	**Same**

Table 3 : Substantial Equivalence EQUIVALENCE DISCUSSION – Technological characteristics – Abutment

	Subject Device	Predicate Device	EQUIVALENCE DISCUSSION
Part Name	Solid Abutment	D Basis Abutment –Direct Type	-
Trade Name	CORE1 Implant System	URIS OMNI System	-
Manufacturer	Cybermed Inc.	Tru Abutment Korea Co., Ltd.	-
510(k) Number	K210039	K172100	-
Usage	It is one body cement retained restoration	It is one body cement retained restoration.	
Type of restoration	Single unit		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined Type	Machined Type	**Same**
Diameter (⌀)	4.0/4.6/5.0/6.0	4.0/4.5/5.5/6.5	**Equivalent** The subject device diameters are in the range of diameters of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence.
Length (mm)	G/H : 1.0/2.0/3.0/4.0/5.0 Post : 4.0/5.5/7.0	G/H :1.0/2.0/3.0/4.0/5.0/6.0 Post : 4.0/5.5/7.0	**Equivalent** The subject device lengths are in the range of diameters of the predicate device. Subject device was verified through performance test, so

			this difference of range doesn't impact substantial equivalence
Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part name	Cement Abutment	Best Duo Abutment	-
Trade Name	CORE1 Implant System	Internal Hex Implant System	-
Manufacturer	Cybermed Inc.	EBI Inc.	-
510(k) Number	K210039	K190837	-
Usage	Using making for general cement-type prosthesis.	Using making for general cement-type prosthesis.	
Type of restoration	Single unit		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined Type	Machined Type	**Same**
Diameter (⌀)	4.0/4.6/5.0/6.0	3.5, 4.0, 4.8, 5.5, 6.5	**Equivalent** The subject device diameters are in the range of diameters of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence.
Length (mm)	Post : 4.0/5.5/7.0	Post : 5.2, 7.2	**Equivalent**

			The subject device lengths are in the range of diameters of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence
Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part Name	Cement Abutment Screw	Abutment Screw	
Trade Name	CORE1 Implant System	OSSTEM Implant System - Abutment	
Manufacture	Cybermed Inc.	OSSTEM Implant Co., Ltd.	
510(k) Number	K210039	K161689	
Usage	It is used to connect and fix the abutment to the fixture tightly.	It is used to connect and fix the abutment to the fixture tightly.	
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined Type	Machined Type	**Same**
Diameter	2.2/2.3	2.0/2.05/2.2/2.3/2.5	**Equivalent** The subject device diameters are in the range of predicate device's diameters.
Length (mm)	8.35/10.2	3.35/5.6/7.5/8.35/9.6/10.2	**Equivalent** The subject device lengths are in the range of diameters of the predicate device. Subject

			device was verified through performance test, so this difference of range doesn't impact substantial equivalence
Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part Name	Angled Abutment	Best Angled Abutment	
Trade Name	CORE1 Implant System	Internal Hex Implant System	
Manufacturer	Cybermed Inc.	EBI Inc.	
510(k) Number	K210039	K190837	
Usage	It is used when a prosthetic's path adjustment is necessary.	It is used when a prosthetic's path adjustment is necessary.	
Type of restoration	Single unit		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined Type	Machined Type	**Same**
Diameter (⌀)	4.0/4.6/5.0/5.5/6.0	3.5/4.0/4.8	**Equivalent** Subject device diameters are within the range of diameters of the predicate and reference devices or larger. Larger diameters do not represent a worst case in terms of performance.
Angle (°)	15/25	15/25	**Same**

Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Reference Device**	**EQUIVALENCE DISCUSSION**
Part name	Milling Abutment	Free Form Abutment	-
Trade Name	CORE1 Implant System	Hiossen Prosthetic System	-
Manufacturer	Cybermed Inc.	OSSTEM Implant co., Ltd.	-
510(k) Number	K210039	K140507	-
Usage	This product is used for marking a final artificial tooth to provide masticatory and aesthetic function and only to hand milled.	This product is used for marking a final artificial tooth to provide masticatory and aesthetic function and only to hand milled.	
Type of restoration	Single unit		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined Type	TiN Coating	**Different** Compared to the predicate device, the subject device's surface treatment is different. This difference of range doesn't impact substantial equivalence.
Diameter (⌀)	4.0/4.6/5.0/5.5/6.0	4.0/5.5/7.0	**Equivalent** The subject device diameters are in the range of diameters of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence.

Length (mm)	G/H : 1.0/2.0/3.0/4.0/5.0	G/H : 0.5/1.0/1.5/2.0/2.5/3.0/4.0/5.0	**Equivalent** Subject devices are within the range of predicate devices diameters
Sterilization	End User Sterilization	End User Sterilization	**Same**
Final design parameters for hand milling	Post Length : 5.0 to 9.0 Total Length : 6.1 to 10.1 Wall thickness : Min 0.4 to Max 1.3 Angulation : Min 0° to 20° Gingival height : 1.0 to 5.0		

	Subject Device	**Predicate Device**	**Reference Device**	**EQUIVALENCE DISCUSSION**
Part Name	Temporary Abutment	Temporary Abutment	Temporary Abutment	-
Trade Name	CORE1 Implant System	SD Abutment	CSM Submerged3-L Implant System	-
Manufacturer	Cybermed Inc.	Surgident Co., Ltd.	CSM Implant	-
510(k) Number	K210039	K173570	K173141	-
Usage	It is used temporarily to maintain esthetic appearance until final prosthesis is made.	It is used temporarily to maintain esthetic appearance until final prosthesis is made.	It is used temporarily to maintain esthetic appearance until final prosthesis is made.	
Type of restoration	Single Unit			
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6AI-4V ELI (ASTM F136), or CP Ti Grade 4 (ASTM F67)	Ti-6Al-4V ELI (ASTM-F136)	**Same**
Surface treatment	Machined type	Machined type	Machined type	**Same**

Diameter (⌀)	4.0/4.6/5.0/5.5/6.0	4.0/4.5/5.0/5.5/6.0/6.5		**Equivalent** The subject device diameters are in the range of diameters of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence.
Length (mm)	12.8/13.8/14.8/15.8/16.8		12.8/13.3/13.8/14.8/15.8/16.8	**Same**
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate Device**	**Reference Device**	**EQUIVALENCE DISCUSSION**
Part Name	Solid Protect Cap	Rigid Protect Cap	Rigid Retraction Cap	
Trade Name	CORE1 Implant System	OSSTEM Implant System – Abutment	OSSTEM Implant System – Abutment	
Manufacturer	Cybermed Inc.	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	
510(k) Number	K210039	K161689	K161689	
Usage	It is used to protect Solid Abutment in the oral cavity.	Used for the protection of the Rigid Abutment in the oral cavity.	Used for the protection of the Rigid Abutment on the oral cavity.	
Material	POM(Polyoxymethylene)	PC(Poly Carbonate Polymer)	POM(Polyoxymethylene)	**Different** Compared to the predicate device, the subject device's raw material is different. However, POM(Polyoxymethylene) and

				PC(Poly Carbonate Polymer) are widely used as medical device material and have proven safe, so these differences do not affect safety and performance.
Diameter (⌀)	4.5/5.1/5.5/6.5	4.4/5.0/5.5/6.6/7.4	4.8/6.0/6.6/7.7/8.7	**Equivalent** The subject device diameters are in the range of diameters of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence.
Length (mm)	5.5/7.0/8.5	5.5/5.7/5.8/5.9/7.0/7.2/7.3/8.5/ 8.7/8.8	5.5/7.0/8.5	**Equivalent** Subject devices are within the range of predicate devices diameters.
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate device**	**EQUIVALENCE DISCUSSION**
Part Name	Cover Screw	Cover Screw	
Trade Name	CORE1 Implant System	Internal Hex Implant System	
Manufacturer	Cybermed Inc.	EBI Inc.	
510(k) Number	K210039	K190837	
Usage	It is to protect exposed top of the fixture, is to	It is to protect exposed top of the fixture, is to be	

	be used in a tooth gap after inserting the implant.	used in a tooth gap after inserting the implant.	
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI Alloy	**Same**
Surface treatment	Anodizing	Anodizing	**Same**
Diameter (⌀)	3.05/3.1/3.25/3.4/3.6	3.0, 3.2, 3.6	**Equivalent** The subject device diameters are in the range of diameters of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence.
Length (mm)	G/H : 0.4, 1.25, 2.25	G/H : 0.4, 1.25, 2.25	**Same**
Sterilization	Gamma Sterilization	Gamma Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part Name	Healing Abutment	IS Healing Abutment	
Trade Name	CORE1 Implant System	IS-III active System	
Manufacturer	Cybermed Inc.	Neobiotech Co., Ltd	
510(k) Number	K210039	K181138	
Usage	It is used with fixture to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue the healing process.	It is used with fixture to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue the healing process.	

Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI of ASTM F136	**Same**
Surface treatment	Machined type	Machined type	**Same**
Diameter (⌀)	4.3/4.8/5.3/6.3/7.3/8.3	4.0/4.5/4.8/5.5/6.0/6.8/8.0/9.0	**Equivalent** The subject device diameters are in the range of diameters of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence.
Length(mm)	G/H: 3.0/4.0/5.0/7.0/9.0	G/H : 2.3/2.8/3.3/3.8/4.3/4.8/5.3/5.8/ 6.3/6.8/7.8	**Equivalent** Subject devices are included in the ranged of the predicate device gingival heights or higher. Higher gingival heights do not represent a worst case in terms of performance.
Sterilization	Gamma Sterilization	Gamma Sterilization	**Same**

	Subject Device	**Predicate Device**	**Reference Device**	**EQUIVALENCE DISCUSSION**
Part Name	Healing Abutment (Scan)	Healing Abutment	BellaTek® Encode® Healing Abutment	
Trade Name	CORE1 Implant System	Internal Hex Implant System	BIOMET 3i Dental Abutments &Restorative Components	
Manufacturer	Cybermed Inc.	EBI Inc.	BIOMET 3i, Inc.	
510(k) Number	K210039	K190837	K072642	
Usage	It is used with fixture to protect	It is used with fixture to protect the	It is used with fixture to protect the	

	the inner configuration of the implant and maintain, stabilize and form the soft tissue the healing process.	inner configuration of the implant and maintain, stabilize and form the soft tissue the healing process.	inner configuration of the implant and maintain, stabilize and form the soft tissue the healing process.	
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined Type	Machined Type	Machined Type	**Same**
Diameter (⌀)	4.0/4.6/5.0/6.0	3.5, 4.0, 4.8, 5.5, 6.5	3.8~7.5	**Equivalent** The subject device diameters are in the range of diameters of the predicate and reference device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence.
Length (mm)	G/H: 3.0/4.0/5.0/6.0/7.0		G/H : 3.0/4.0/6.0/8.0	**Equivalent** The subject device lengths are in the range of lengths of the reference device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**

Part Name	Healing Abutment (Scan) Screw	Abutment Screw	
Trade Name	CORE1 Implant System	OSSTEM Implant System - Abutment	
Manufacturer	Cybermed Inc.	OSSTEM Implant Co., Ltd.	
510(k) Number	K210039	K161689	
Usage	It is used for connecting Healing Abutment(Scan) to Fixture	It is used for connecting Abutment to Fixture	
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined Type	Machined Type	**Same**
Diameter (Ø)	2.2/2.3	2.0/2.05/2.2/2.3/2.5	**Equivalent** Subject devices are within the range of predicate devices diameters.
Length (mm)	9.0/10.7	3.35/5.6/7.5/8.35/9.6/10.2	**Equivalent** The subject device lengths are in the range of lengths of the predicate and reference device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence
Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part Name	Universal Abutment	Multi-unit Abutment Straight	
Trade Name	CORE1 Implant System	IH Prosthetic System	

Manufacturer	Cybermed Inc.	Sewon Medix Inc.	
510(k) Number	K210039	K153521	
Usage	It is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation	It is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation	
Type of restoration	Multi unit		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined Type	Machine	**Same**
Diameter (Ø)	4.8	4.8	**Same**
Length (mm)	G/H : 2.0/3.0/4.0/5.0	G/H : 1.5/ 2.5 / 3.5 / 4.5	**Equivalent** The subject device lengths are in the range of lengths of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence
Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part Name	Universal Angled Abutment	Multi-Unit Abutment	
Trade Name	CORE1 Implant System	Internal Hex Implant System	
Manufacturer	Cybermed Inc.	EBI Inc.	

510(k) Number	K210039	K190837	
Usage	It is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation and used the multi-unit only.	It is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation and used the multi-unit only.	
Type of restoration	Multi unit		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined Type	Machined type	**Same**
Diameter (Ø)	4.8	4.8	**Same**
Length (mm)	G/H : 2.0/3.0/4.0/5.0	G/H : 1.0/2.0/2.5/3.0/3.5/4.0/5.0	**Equivalent** Subject devices are within the range of predicate device's lengths.
Angle (˚)	17/30	0/17/30	**Equivalent**
Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part Name	Universal Angled Abutment Screw	Abutment Screw	
Trade Name	CORE1 Implant System	OSSTEM Implant System – Abutment	
Manufacturer	Cybermed Inc.	OSSTEM Implant Co., Ltd	
510(k) Number	K210039	K161689	

Usage	It is used for connecting Universal Angled Abutment to the Fixture.	It is used for connecting Abutment to the Fixture.	
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined Type	Machined Type	**Same**
Diameter (Ø)	2.2	2.0/2.05/2.2/2.3/2.5	**Equivalent** Subject devices are within the range of predicate device's diameters.
Length (mm)	8.35/10.2	3.35/5.6/7.5/8.35/9.6/10.2	**Equivalent** Subject devices are within the range of predicate device's lengths.
Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part Name	Universal Ti Cylinder	Convertible Combination Cylinder	
Trade Name	CORE1 Implant System	ET/SS Implant System	
Manufacturer	Cybermed Inc.	OSSTEM Implant Co., LTD	
510(k) Number	K210039	K120847	
Usage	It creates framework of the final prosthesis to be fixed on top of the abutment.	It creates framework of the final prosthesis to be fixed on top of the abutment.	
Material	Ti-6Al-4V ELI (ASTM F136)	Titanium Gr.3 (ASTM F67)	**Different** The subject device has the different Material as the predicate device. But both raw materials are

			well-established because of their good biocompatibility performance.
Surface treatment	Machined Type	Machined Type	**Same**
Diameter (Ø)	4.8	4.2~6.3	**Equivalent** The subject device diameters are in the range of diameters of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence.
Length (mm)	7.0	7.0	**Same**
Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part Name	Universal Ti Cylinder Screw	Abutment Screw	
Trade Name	CORE1 Implant System	OSSTEM Implant System – Abutment	
Manufacturer	Cybermed Inc.	Osstem Implant Co., Ltd.	
510(k) Number	K210039	K161689	
Usage	It is used for connecting Universal Ti Cylinder, Universal Temporary Cylinder, Universal Plastic Cylinder or Universal Healing Cap used with Universal Abutment or Universal Angled Abutment.	It is used for connecting Abutment to the Fixture.	

Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined type	Machined type	**Same**
Diameter (Ø)	2.2	2.0/2.05/2.2/2.3/2.5	**Equivalent** The subject device diameters are in the range of diameters of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence.
Length (mm)	4.0	3.35/5.6/7.5/8.35/9.6/10.2	**Equivalent** The subject device lengths are in the range of lengths of the predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence
Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part Name	Universal Temporary Cylinder	Multi-Unit Temporary Cylinder	-
Trade Name	CORE1 Implant System	Internal Hex Implant System	-
Manufacturer	Cybermed Inc.	EBI Inc.	-
510(k) Number	K210039	K190837	-
Usage	It is for temporary prosthesis for use with the	It is for temporary prosthesis for use with	

	Universal Abutment.	Multi-Unit Abutment.	
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI Alloy	**Same**
Surface treatment	Machined type	Machined type	**Same**
Diameter (Ø)	4.8	4.8	**Same**
Length (mm)	12	12	**Same**
Sterilization	End User Sterilization	End User Sterilization	**Same**

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part Name	Universal Healing Cap	Multi-Unit Healing Cap	
Trade Name	CORE1 Implant System	Internal Hex Implant System	
Manufacturer	Cybermed Inc.	EBI Inc.	
510(k) Number	K210039	K190837	
Usage	It is lead to accurate closure of soft tissue surrounding implant and provide a definite shape and form to gingival which is aesthetically close to natural look.	It is lead to accurate closure of soft tissue surrounding implant and provide a definite shape and form to gingival which is aesthetically close to natural look.	
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	**Same**
Surface treatment	Machined Type	Machined type	**Same**
Diameter (Ø)	4.8	4.9, 6.2	**Different** The subject device diameter is different from predicate device. Minor differences in the

			dimensions are not expressed to impact substantial equivalence because the device is only intended during healing for protection and designed for compatibility to the associated abutment.
Length (mm)	5.5	4.2	**Different** The subject device length is different from predicate device. Minor differences in the dimensions are not express to impact substantial equivalence because the device is only intended during healing for protection and designed for compatibility to the associated abutment.
Sterilization	Gamma Sterilization	End User Sterilization	**Different** The subject device sterilization is different from predicate device. Subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence

	Subject Device	**Predicate Device**	**EQUIVALENCE DISCUSSION**
Part Name	Universal Plastic Cylinder	Octa Plastic Cylinder	
Trade Name	CORE1 Implant System	Internal Hex Implant System	
Manufacturer	Cybermed Inc.	EBI Inc.	
510(k) Number	K210039	K190837	
Usage	It is a burn-out device only used in the lab for	It is a burn-out device only used in the lab for	

	casting and is not part of the final restoration.	casting and is not part of the final restoration.	
Material	POM(Polyoxymethylene)	POM(Polyoxymethylene)	**Same**
Diameter (Ø)	4.8	5.0	**Different** The subject device diameter is different from predicate device, but this difference is not important factor to the device performance. The subject device is substantial equivalent.
Length (mm)	12	10.0	**Different** The subject device length is different from predicate device, but this difference is not important factor to the device performance. The subject device is substantial equivalent.
Sterilization	End User Sterilization	End User Sterilization	**Same**

K161244(s-Clean OneQ-SL Narrow Implant System), K190837 (Internal Hex Implant System) and K123988(Xpeed AnyRidge Internal Implant System) are chosen to support additional fixture dimensions (diameter x length combinations) that are not covered by primary predicate K153639. s-Clean OneQ-SL Narrow Implant System K161244 was included for the additional indications for use language specific to our 3.3mm diameter implants. Other reference devices (K172100, K161689, K140507, K173570, K173141, K181138, K072642, K153521, K120847) were chosen because K153936 does not include all abutments which is equivalent with ours. We chose considering indication for use, design, material, principle of operations, dimension, length, or angulation for various abutment models. Minor differences in the dimension or length are not expected to impact substantial equivalence because subject device diameters are in the range of diameters either predicate or reference devices. Also, subject device was verified through performance test, so this difference of range doesn't impact substantial equivalence.

Therefore, any difference doesn’t impact the substantial equivalence.

VII. NON-CLINICAL TESTING

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

• Bacterial endotoxin test performed according to The United States Pharmacopoeia (USP) <85><161> and ANSI/AAMI ST72:2011 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing. The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on a blood contacting and implanted device. As a result of endotoxin test validation for the product, it was confirmed that the endotoxin test reagent (PTS cartridge) and the laboratory environment were suitable for endotoxin test by the initial qualification test. Endotoxin Test concludes that the product is suitable for endotoxin testing using both PTS readers and PTS cartridge, meeting both endotoxin standards and established criteria for testing.

• Fatigue Testing performed according to ISO 14801:2016 and FDA guidance document “Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments”. Comparative fatigue testing was performed subject device and reference device K190837 to confirm covering permanent restoration of the implant without failure.

• Surface Analysis performed by SEM & EDS. Analysis results indicated that there was surface roughness leading to a macroroughness and no other impurity on the surface of the final product.

• Gamma sterilization validation performed according to ISO 11137-1:2006/Amd.1:2013 Sterilization of health care products -Requirements for validation and routine control – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, ISO 11137-2:2013 Sterilization of health care products -Requirements for validation and routine control – Radiation – Part 2 : Establishing the sterilization dose, and ISO 11137-3:2006 Sterilization of health care products -Requirements for validation and routine control – Radiation – Part 3 : Guidance on dosimetric aspects. It was acceptable range of densities of other product in carrier and confirm to process

stability. Based on these, the packaging with gamma sterilization of the subject is equivalent to the packaging of the predicate and reference device. The shelf life for devices provided sterile is 5 years.

• End user sterilization for abutment performed according to ISO 17665-1:2006 "Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices", ISO 17665-2:2009 "Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1"and ANSI/AAMI ST79:2010/A4:2013 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities, Amendment 3"

• Biocompatibility testing performed according to ISO 10993-1:2018 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" and to the FDA Guidance document "Use of International Standard ISO 10993- 1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff, Document issued on: September 4, 2020" for each of the subject devices, and ISO 10993-5:2009 "Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity".

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

VIII. SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject device, CORE1 implant system, has same device characteristics with the primary predicate and reference devices as dental implant system. It is intended purpose as they are placed in the alveolar bone to replace the function of missing tooth.

The various dimensions of subject devices are slightly different from the predicate devices. However, the dimensions of the subject device are in the range of the dimensions of the predicate and reference devices. Also, subject device was verified through performance test, so this difference of range doesn't impact substantial

equivalence. The bench and biocompatibility testing performed demonstrates that any differences in their technological characteristics doesn't impact substantial equivalence.

Therefore, it is concluded that CORE1 implant system is substantially equivalent to the predicate devices.