CSM Implant
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

September 19, 2019

Re: K173141
Trade/Device Name: CSM Submerged3-L Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 17, 2018
Received: August 22, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Mary S. Runner -S3

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

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)*
K173141

Device Name
CSM Submerged3-L Implant System

Indications for Use *(Describe)*
The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. 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: CSM Submerged3-L 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: 09/17/2018

Predicate Information

Primary Predicate:
K102635, CSM Submerged-L Implant System by CSM Implant

Reference Predicate:
K143022, BioHorizons Tapered Internal Implants by BioHorizons Implant System Inc.
K120043, CSM Internal-R Implant System by CSM Implant
K081575, HU/HS/HG PROSTHETIC SYSTEM by Osstem Implant
K112787, Karator by KJ Meditech Co, Ltd.

Device Description

The CSM Submerged3-L Implant System is composed of dental fixtures (Sub3 Fixture) and various abutments such as Healing Abutment, Cementation Abutment (Hex, Non-Hex), Angled Abutment (Hex, Non-Hex), Abutment Screw, Submerged Cover Screw, Retainer Abutment, Retainer Cap, Retainer Retention Male, and Temporary Abutment (Hex, Non-Hex).
There is no vertical anti-rotation slot in our fixtures. When it comes to anti-rotational feature, it is 11 °, which is internal hexagonal feature. Hence, 4.0, 4.4, 4.8, 5.2, 5.6, 6.0 size fixtures have 2.5 hexagonal features, different from fixture with 3.6 diameter, which has 2.1 double hexagonal feature. The fin of submerged 3 fixtures is V-shape. In addition, a straight flat axial surface is on our fixture, functioning as tapering part.

In case of abutments, 2.5 and 2.1 hexagonal features are usually used.

The Sub3 fixtures and screws are made of Ti 6Al 4V ELI (Conforming to ASTM Standard F-136) and dental abutment is made of Ti-6Al-4V ELI (ASTM F136), POLYAMIDE 6.6.

The surface of the fixtures is treated with RBM (Resorbable Blast Media) and Laser.

The diameters of the CSM Submerged3-L Implants are Ø 3.62mm, 3.95mm, 4.35mm, 4.75mm, 5.15mm, 5.55mm, 5.95mm and the lengths of the CSM Submerged3-L Implants are 7.3mm, 8.3mm, 9.3mm, 10.3mm, 11.3mm, 12.3mm, 13.3mm, 14.3mm.

The dimension of each abutment ranges as below:(The tolerance of all products is ±0.03)

- Healing Abutment: Ø 4.02mm, 4.5mm, 5.5mm, 6.5mm (D) X 8.25mm, 8.75mm, 9.75mm, 10.35mm, 10.75mm, 11.75mm, 12.35mm, 12.75mm (L)
- Cementation Abutment: Ø 4.5mm, 5.5mm, 6.5mm (D) X 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.5mm, 11.5mm, 12.5mm, 13.5mm (L)
- Angled Abutment: Ø 4.0mm, 4.5mm, 5.5mm (D) X 9.0mm, 9.4mm, 9.5mm, 10.0mm, 10.3mm, 10.4mm, 10.5mm, 11.3mm, 11.4mm, 11.5mm, 12.3mm, 12.5mm, 13.3mm, 13.5mm (L) with 15° and 20°
- Abutment Screw: Ø 2.1mm, 2.33mm (D) X 8.3mm, 10.0mm (L)
- Submerged Cover Screw: Ø 2.83mm, 3.33mm (D) X 6.0mm, 6.5mm (L)
- Retainer Abutment: Ø 3.9mm (D) X 7.15mm, 7.4mm, 7.65mm, 7.9mm, 8.65mm, 8.9mm, 9.65mm, 9.9mm, 10.65mm, 10.9mm, 11.65mm, 11.9mm, 12.65mm, 12.9mm, 13.65mm, 13.9mm, 14.65mm, 14.9mm, 15.65mm, 15.9mm, 16.65mm, 16.9mm (L)
- Retainer Cap: Ø 5.45mm (D) X 2.4mm (L)
- Retainer Retention Male: Ø 4.7mm (D) X 1.85mm, 2.06mm (L)
- Temporary Abutment: Ø 4.5mm, 5.5mm (D) X 12.8mm, 13.3mm, 13.8mm, 14.8mm, 15.8mm, 16.8mm (L)

The implant-abutment connection is internal hex and Morse taper level.
Implant-fixture and submerged cover screw are packed together and provided sterile. The abutments are provided non-sterile and must be sterilized before use.

Indication for Use

The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.

Materials:

The Sub3 fixtures and screws are made of Ti-6Al-4V ELI (Conforming to ASTM Standard F136-13) and dental abutments are made of Ti-6Al-4V ELI (Conforming to ASTM Standard F136-13), POLYAMIDE 6.6.

Summary of Technological Characteristics

1) Fixtures

		Subject Device	Primary Predicate	Reference Predicate
510(K) Number		K173141	K102635	K143022
Device Name		CSM Submerged3-L Implant System	CSM Submerged-L Implant System	BioHorizons Tapered Internal Implants
Manufacturer		CSM Implant	CSM Implant	BioHorizons Implant Systems, Inc.
Indications for Use		The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.	CSM Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.	Bio Horizons Tapered Internal Implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. Bio Horizons Tapered Internal Implants may be restored immediately I) with a temporary prosthesis that is not in functional occlusion, or 2) when splinted together for multiple tooth replacement, or when stabilized with an overdenture supported by multiple implants
Appearance				
Material		Ti-6Al-4V ELI (ASTM-F136)	Ti-6Al-4V ELI (ASTM-F136)	Ti-6Al-4V ELI (ASTM-F136)
Sterilization		Gamma	Gamma	Gamma
Surface Treatment		RBM(Resorbable Blasting Media) + Laser	RBM(Resorbable Blasting Media) + Laser	Implant- RBT Collar- Laser-Lok or RBT
Implant	Diameter	3.62mm, 3.95mm, 4.35mm, 4.75mm, 5.15mm, 5.55mm, 5.95mm	3.5-6.0mm	3.4mm, 3.8mm, 4.6mm
	Length	7.3mm, 8.3mm, 9.3mm, 10.3mm, 11.3mm, 12.3mm, 13.3mm, 14.3mm	7-14mm	9mm, 10.5mm, 12mm, 15mm, 18mm
connection		Internal	Internal	Internal
Shelf Life		5 years	5 years	5 years
Principle of Operation		Dental implant that can be inserted on a jawbone as a material for dental surgery to support	Dental implant that can be inserted on a jawbone as a material for dental surgery to support	Dental implant that can be inserted on a jawbone as a material for dental surgery to support

Similarities	The indications for use, material, general shape design, dimension, surface treatment, Principle of operation, shelf life and sterilization method between the CSM Submerged3-L Implant System and the predicate devices are identical.
Differences	Fixture's micro-threaded part: The primary predicate, K102635 has micro threaded part on the fixture whereas the subject device has no micro thread part. To support this discrepancy, we chose K143022 as a reference predicate. Accordingly, we can claim the substantially equivalence of the CSM Submerged3-L Implant System to predicate devices.

2) Abutments

- K102635, CSM Submerged-L Implant System by CSM Implant
- K120043, CSM Internal-R Implant System by CSM Implant
- K081575, HU/HS/HG PROSTHETIC SYSTEM by Osstem Implant
- K112787, Karator by KJ Meditech Co, Ltd.

<Healing Abutment>

	Subject Device	**Predicate Device**
510(K) Number	K173141	K102635
Device Name	CSM Submerged3-L Implant System	CSM Submerged-L Implant System
Manufacturer	CSM Implant	CSM Implant
Indications for Use	The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.	CSM Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.
Material	Ti-6Al-4V ELI (ASTM-F136)	Ti-6Al-4V ELI (ASTM-F136)
Diameter	4.02mm, 4.5mm, 5.5mm, 6.5mm	4.02mm, 4.52mm, 5.52mm, 6.52mm
Length	8.25mm, 8.75mm, 9.75mm, 10.35mm, 10.75mm, 11.75mm, 12.35mm, 12.75mm	8.55mm, 8.75mm, 9.25mm, 9.35mm, 10.75mm, 11.35mm, 11.75mm, 12.75mm
Appearance		
Principle Operation	Linked to fixture, this has covered the joint of fixture until gingiva recovers.	Linked to fixture, this has covered the joint of fixture until gingiva recovers.
Similarities	The indications for use, material, general shape design, dimension, surface treatment, Principle of operation, and shelf life are identical.	
Differences	The diameters and lengths of the subject device are slightly different from the predicate device. However, the predicate device includes healing abutments that meet or exceed the diameter and total height range compared to the dimensions of the subject device. Therefore, the subject device is substantially equivalent.	

<Cementation Abutment>

	Subject Device	**Predicate Device**
510(K) Number	K173141	K102635
Device Name	CSM Submerged3-L Implant System	CSM Submerged-L Implant System
Manufacturer	CSM Implant	CSM Implant
Indications for Use	The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.	CSM Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.
Material	Ti-6Al-4V ELI (ASTM-F136)	Ti-6Al-4V ELI (ASTM-F136)
Diameter	4.5mm, 5.5mm, 6.5mm	4.0mm, 4.5mm, 5.5mm, 6.5mm
Length	8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.5mm, 11.5mm, 12.5mm, 13.5mm	8.8mm, 9.45mm, 9.5mm, 10.3mm, 10.45mm, 11.3mm, 11.45mm,12.3mm
Appearance		
Principle Operation	Abutment used to fix crown, after being engaged with fixture.	Abutment used to fix crown, after being engaged with fixture.
Similarities	The indications for use, material, general shape design, dimension, surface treatment, Principle of operation, and shelf life are identical.	
Differences	The length and diameters of two devices are slightly different. However, the dimensional differences of these devices do not have any influence on the Substantial equivalence, since it is within the legend of predicate, and the indications, principle of operations and raw material are identical.	

<Angled Abutment>

	Subject Device	**Predicate Device**
510(K) Number	K173141	K102635
Device Name	CSM Submerged3-L Implant System	CSM Submerged-L Implant System
Manufacturer	CSM Implant	CSM Implant
Indications for Use	The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.	CSM Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.
Material	Ti-6Al-4V ELI (ASTM-F136)	Ti-6Al-4V ELI (ASTM-F136)
Diameter	4.0mm, 4.5mm, 5.5mm	4.5~5.5mm
Length	9.0mm, 9.4mm, 9.5mm, 10.0mm, 10.3mm,10.4mm, 10.5mm, 11.3mm, 11.4mm, 11.5mm, 12.3mm, 12.5mm, 13.3mm, 13.5mm	15.31mm

Appearance		
Angulation	15º, 20º	15º, 20º
Principle Operation	Abutment used to form right connection between crown and fixture inserted diagonally	Abutment used to form right connection between crown and fixture inserted diagonally
Similarities	The indications for use, material, general shape design, dimension, surface treatment, Principle of operation, and shelf life are identical.	
Differences	The diameters and lengths of the subject device are slightly different from the predicate device. However, the predicate device includes Angled Abutments that meet or exceed the diameter and total height range compared to the dimensions of the subject Angled Abutments. Therefore, the subject device is substantially equivalent.	

<Abutment Screw>

	Subject Device	**Predicate Device**
510(K) Number	K173141	K102635
Device Name	CSM Submerged3-L Implant System	CSM Submerged-L Implant System
Manufacturer	CSM Implant	CSM Implant
Indications for Use	The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.	CSM Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.
Material	Ti-6Al-4V ELI (ASTM-F136)	Ti-6Al-4V ELI (ASTM-F136)
Diameter	2.1mm, 2.33mm	2.1mm, 2.33mm
Length	8.3mm, 10.0mm	8.6mm, 10.8mm
Appearance		
Principle Operation	Screw used to link abutment to fixture	Screw used to link abutment to fixture
Similarities	The indications for use, material, general shape design, dimension, surface treatment, Principle of operation, and shelf life are identical.	
Differences	The diameters and lengths of the subject device are slightly different from the predicate device. However, the predicate device includes Abutment screws that meet or exceed the diameter and total height range compared to the dimensions of the subject Abutment Screws. Therefore, the subject device is substantially equivalent.	

<Submerged Cover Screw>

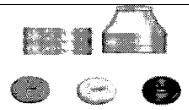
	Subject Device	**Predicate Device**
510(K) Number	K173141	K102635
Device Name	CSM Submerged3-L Implant System	CSM Submerged-L Implant System
Manufacturer	CSM Implant	CSM Implant
Indications for Use	The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.	CSM Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.
Material	Ti-6Al-4V ELI (ASTM-F136)	Ti-6Al-4V ELI (ASTM-F136)
Diameter	2.83mm, 3.33mm	2.83mm, 3.33mm
Length	6.0mm, 6.5mm	6mm, 6.5mm
Appearance		
Principle Operation	Screw used to cover the joint of fixture to prevent foreign matter from entering.	Screw used to cover the joint of fixture to prevent foreign matter from entering.
Similarities	The indications for use, material, general shape design, dimension, surface treatment, Principle of operation, and shelf life are identical.	
Differences	These two products are substantially identical.	

<Retainer Abutment>

	Subject Device	**Predicate Device**
510(K) Number	K173141	K112787
Device Name	CSM Submerged3-L Implant System	Kerator
Manufacturer	CSM Implant	KJ Meditech Co, Ltd.
Indications for Use	The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.	The Kerator is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.
Material	Ti-6Al-4V ELI (ASTM-F136)	Ti-6Al-4V ELI (ASTM-F136)
Diameter	3.9mm	3.86mm
Length	7.15mm, 7.4mm, 7.65mm, 7.9mm, 8.65mm, 8.9mm, 9.65mm, 9.9mm, 10.65mm, 10.9mm, 11.65mm, 11.9mm, 12.65mm, 12.9mm, 13.65mm, 13.9mm, 14.65mm, 14.9mm, 15.65mm, 15.9mm, 16.65mm, 16.9mm	9mm,9.6mm
Appearance		
Principle Operation	Abutment used to link overdenture to gingiva.	Abutment used to link overdenture to gingiva.

Similarities	The main similarities between these two items are indication for use, and materials.
Differences	Even though these are dimensional differences, the different sizes of two products do not have any influences on the substantial equivalence, as the Indications principles and the raw materials are equivalent.

<Retainer Cap>

	Subject Device	**Predicate Device**
510(K) Number	K173141	K081575
Device Name	CSM Submerged3-L Implant System	O-Ring Retainer Cap set (HU/HS/HG PROSTHETIC SYSTEM)
Manufacturer	CSM Implant	OSSTEM Implant
Indications for Use	The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.	HU/HS/HG Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Material	Ti-6Al-4V ELI (ASTM-F136)	Titanium / Silicone
Diameter	5.45mm	5.45mm
Length	2.4mm	2.35mm
Appearance		
Principle Operation	Cap used to link overdenture to retainer abutment.	Cap used to link overdenture to retainer abutment.
Similarities	The main similarities of these two items are indications for use and how to function.	
Differences	Even though these are dimensional differences, the different sizes of two products do not have any influences on the substantial equivalence, as the indications, principles, and the raw materials are equivalent.	

<Retainer Retention Male>

	Subject Device	**Predicate Device**
510(K) Number	K173141	K112787
Device Name	CSM Submerged3-L Implant System	Kerator
Manufacturer	CSM Implant	KJ Meditech Co, Ltd.
Indications for Use	The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.	The Kerator is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.
Material	POLYAMIDE 6.6	DuPont Zytel 101L NC-10 Nylon Low Density Polyethelene 993
Diameter	4.7mm	4.8mm
Length	1.85mm, 2.06mm	1.48mm
Appearance		

Patient contact	No	No
Principle Operation	Retention cap used to connect overdenture with retainer abutment by being located in retainer cap.	Retention cap used to connect overdenture with retainer abutment by being located in retainer cap.
Similarities	The simiarities between these two items are indication for use and the way to be placed.	
Differences	The differences of these two products are material and the sizes. Since these products are no patient contact device, the difference of material doesn't influence the substantial equivalence and since both products have similar indications, same principle of operations, the differences of sizes do not influence the substantial equivalence with the predicate.	

<Temporary Abutment>

	Subject Device	**Predicate Device**
510(K) Number	K173141	K120043
Device Name	CSM Submerged3-L Implant System	CSM Internal-R Implant System
Manufacturer	CSM Implant	CSM Implant
Indications for Use	The CSM Submerged3-L Implant System is intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. This system is intended for delayed loading.	The CSM Internal-R 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 intended for delayed loading.
Material	Ti-6Al-4V ELI (ASTM-F136)	Ti-6Al-4V ELI (ASTM-F136)
Diameter	4.5mm, 5.5mm	4.5mm, 5.5mm
Length	12.8mm, 13.3mm, 13.8mm, 14.8mm, 15.8mm, 16.8mm	12.8mm, 13.3mm, 13.8mm, 14.8mm, 15.8mm, 16.8mm
Appearance		
Principle Operation	Abutment fastened to fixture for working model with torx driver	Abutment fastened to fixture for working model with torx driver
Similarities	The indications for use, material, dimension, surface treatment, Principle of operation, shelf life are identical.	
Differences	The shape of two devices is different but there is no influence on the substantial equivalance because they have similar indications for use and same materials, prinicple of operations and dimensions.	

Similarities

The indications for use, material, general shape design, dimension, surface treatment, connection to abutment method, application method and sterilization method between the CSM Submerged3-L Implant System and the predicate devices are similar.

Differences

1) Fixture's micro-threaded part: The primary predicate, K102635 has micro threaded part on the fixture whereas the subject device has no micro thread part. To support this discrepancy, we chose K143022 as a reference predicate.
2) There are lots of new abutments compared to the primary predicate, K102635. To prove substantial equivalence, reference predicate devices such as K052272, K081575, and K112787 are chosen.

Accordingly, we can claim the substantially equivalence of the CSM Submerged3-L Implant System to predicate devices.

Non-Clinical Data:

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

- End User Steam Sterilization Test according to ISO 17665-1:2006, -2:2009 and ANSI/AAMI ST79
- Biocompatibility Test such as cytotoxicity according to ISO 10993-5:2009, irritation according to ISO 10993-10:2010, sensitization according to ISO 10993-10:2010, acute systemic according to ISO 10993-11:2006, and genotoxicity according to ISO 10993-3:2014.

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

- Sterilization Validation Test according to ISO 11137-1,2,3 referenced in K102635.
- Fatigue Test according to ISO 14801 referenced in K102635.
- Accelerated Aging Test (Shelf Life Test) according to ASTM F1980-07 referenced in K102635.

The end user sterilization test was performed for the subject abutments.
The sterilization validation test was performed for the predicate, K102635 and leveraged for the subject product because the product material, sterilization site, sterilization method, SAL, sterilization parameters are exactly identical to the predicate, K102635.
The biocompatibility tests were performed on the subject device and it demonstrated the subject device is biocompatible.
The accelerated aging testing was performed for predicate device, K102635 and leveraged for the subject device because the product category, material, manufacturing process, facility, packaging material and packaging procedure are the exactly the same as the predicate, K102635.
The fatigue testing was performed for the predicate device, K102635 and leveraged for the subject device because we compared the worst-case implants and abutments and the test sample from K102635 was the worst. Therefore, it supports mechanical properties.
The results of the above tests have met the criteria of the standards, and demonstrated the substantial equivalence with the predicate device and are compliant with Guidance of "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant abutments".

Conclusion

The CSM Submerged3-L 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, CSM Submerged3-L Implant System, and its predicates are substantially equivalent.