July 23, 2025

ARUM DENTISTRY Co., Ltd.
Won-Yi Choi
Official Correspondent
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
REPUBLIC OF KOREA

Re: K250280
Trade/Device Name: SD TL Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 31, 2025
Received: June 18, 2025

Dear Won-Yi Choi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250280

Device Name
SD TL Implant System

Indications for Use *(Describe)*
The SD TL 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. Abutments are indicated for screw-retained single restorations or cement-retained single of multi-unit restorations. SD TL Implant System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. All digitally-designed abutments are intended to be sent to an ARUM DENTISTRY validated milling center for manufacture.

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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7. 510(K) Summary

Submitter

ARUM DENTISTRY Co., Ltd.
Won-Yi Choi
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
Republic of Korea
Email: arum_ra@arumdentistry.com
Tel. +82-42-935-3644
Fax. +82-42-935-3633

Device Information

- Trade Name: SD TL Implant System
- Common Name: Implant, Endosseous, Root-Form
- Classification Name: Endosseous Dental Implant
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: 07/23/2025

Predicate Devices

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

Primary Predicate

- K242753, SD TL Implant System by Arumdentistry Co., Ltd.

Reference Device

- K193425, Pre-Milled Blank by Arumdentistry Co., Ltd.
- K213506, NB 1 SA Implant System by Arumdentistry Co., Ltd.
- K241703, SD Implant Abutment by Arumdentistry Co., Ltd.
- K240091, NB Mini Implant System by Arumdentistry Co., Ltd.
- K212517, Magicore System by InnoBioSurg Co., Ltd.
- K212702, IM/ST Fixture System by Guilin FiTeeth Medical Instrument Co., Ltd.
- K231753, Oneday Implant Abutment by Oneday Biotech Co., Ltd.
- K233450, Healing Cap, MegaGen Implant Co., Ltd.

General Description

SD TL Implant System consist of below:

Fixture

- SD Tissue Level Fixture
- SD Bone Level Fixture

Abutment

- Multi Angled Cylinder
- Multi Digital Cylinder
- Multi Ti Cylinder
- Multi Healing Cap
- Healing Abutment
- Temporary Abutment

Device Description

1) Fixture

This product is a dental implant which is placed into alveolar bone to replace the function of missing teeth. To enhance the osseointegration with the alveolar bone, this titanium dental implant is treated with SLA (Sandblasted with Large-grit and Acid-etching). As a dental implant which is placed into alveolar bone to support dental prostheses such as artificial teeth used to rehabilitate a patient's masticatory function, the product is used as a substructure implanted into the human body.

An endosseous dental implant is a device made of a material as Pure Titanium (Conforming to ASTM F67) which will be placed in the alveolar bone to replace the function of the missing tooth. The SD TL Implant System consists of dental implants, abutments for use in one or two-stage dental implant placement and restorations.

The implant-abutment connection is tight and precise fitting with non-submerged external connection and with submerged internal connection. The surface of the fixture 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 devices or other components of a dental implant set with human body (mandibular or maxillary bone).

The dimension ranges of the subject device are below:

No.	Device Name	Dimension
1	SD Tissue Level Fixture	Ø3.7, 4.2, 4.6, 5.0 (D) x 7.0, 8.5, 10.0, 11.5, 13.0 mm (L)
2	SD Bone Level Fixture	Ø6.48 (D) x 7.0, 8.5, 10.0, 11.5 mm (L)

2) Abutment

The abutment is made of Ti-6Al-4V Eli (Conforming to ASTM F136) to be used in fabricating patient-specific abutments. The subject devices are indicated for cemented or screw-and cement retained prosthesis (SCRP) restorations. Each patient-specific abutment is individually prescribed by the clinician. The Multi Angled cylinders come in engaging and non-engaging types.

No.	Device Name	Dimension
1	Multi Angled Cylinder	Ø5.5 (D) x 9.5, 10.5 mm
2	Multi Digital Cylinder	Ø5.5 (D) x 6.5, 7.5, 8.5, 9.5 mm
3	Multi Ti Cylinder	Ø4.8 (D) x 4.5 mm Ø5.5 (D) x 8.0, 9.0 mm
4	Multi Healing Cap	Ø4.8, 5.7 (D) x 4.35, 5.85, 7.35 mm
5	Healing Abutment	Ø3.5, 3.67, 4.2, 5.2, 6.2, 7.5, 8.5 (D) x 6.9 ~ 13.3mm
6	Temporary Abutment	Ø3.7, 4.0 (D) x 10.4, 10.45, 12.4, 12.45 mm

Tolerance of dimension shall be within ± 1% range.

Multi Digital Cylinder and Multi Ti Cylinder are used as part of a two-piece abutment, where the base is premanufactured from titanium alloy (Ti-6Al-4V Eli) and the top half is a CAD/CAM zirconia superstructure, milled at a validated milling center.

These pieces are cemented together to form the final abutment.

The Titanium Base abutment is composed of two-piece abutment that is a titanium base at the bottom and a zirconia superstructure (CAD/CAM patient specific superstructure) at the top. The zirconia superstructure is straight only and is not to be designed to provide an angle or divergence correction.

For the Multi Digital Cylinder and Multi Ti Cylinder the design parameters for the CAD/CAM zirconia superstructure are:

Minimum wall thickness – 0.5 mm;

Minimum post height for single-unit restorations – 4.5 mm;

Maximum gingival height – 5.0 mm;

Minimum gingival height – 0.5 mm;

Angulation - 0°

* The post height is defined as measured above the gingival height of the final patient-matched design.

The digital workflow requires the use of the following equipment:

- Restorative Material: Non-Sterile Zirconia Block (K190112)
- Dental Cement: U-Cem Premium & MAZIC Cem (K193260)

The SD TL Implant System is compatible with the SD Bone Level Fixtures and NB Implant Systems. (as the below table).

Manufacturer	510(k) No.	Implant system Compatibility	Dimension
ARUM DENTISTRY Co., Ltd.	K213506	NB 1 SA Implant System	Ø 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5
	K230725	NB Implant System	Ø 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5
	K240091	NB Mini Implant System	Ø 3.2, 3.5
	K241703	SD Implant System	Ø 3.3, 3.7, 4.2, 4.35, 4.6, 4.75, 5.0, 5.15, 6.2
	K242753	SD TL Implant System	Ø 4.8

Indication for Use

The SD TL 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. Abutments are indicated for screw-retained single restorations or cement-retained single of multi-unit restorations. SD TL Implant System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. All digitally-designed abutments are intended to be sent to an ARUM DENTISTRY validated milling center for manufacture.

Materials

The Fixtures are fabricated from Pure Titanium (Conforming to ASTM F67).
One-piece abutment and Screws are fabricated from Ti-6Al-4V Eli (Conforming to ASTM F136).
The two-piece abutments are fabricated from Ti-6Al-4V Eli (Conforming to ASTM F136) as the metallic base component mated with zirconia superstructures fabricated from Zirconium Oxide (ZrO_2) as the top-half component.

Summaries of Technology Characteristics

1) SD Tissue Level Fixture

	Subject Device	Primary Predicate	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.	InnoBioSurg Co., Ltd.
Device Name	SD Tissue Level Fixture	SD TL Implant System	Magicore System
510(k) Number	K250280	K242753	K212517
Intended Use/ Indications for use	The SD TL 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. Abutments are indicated for screw-retained single restorations or cement-retained single of multi-unit restorations. SD TL Implant System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. All digitally-designed abutments are intended to be sent to an ARUM DENTISTRY validated milling center for manufacture.	The SD TL 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. Abutments are indicated for screw-retained single restorations or cement-retained single of multi-unit restorations. SD TL Implant System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. All digitally-designed Pre-Milled Abutments are intended to be sent to an ARUM DENTISTRY validated milling center for manufacture.	The Magicore System is intended to replace missing teeth to restore chewing function. The Magicore System can be placed in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.
Material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Ti-6Al-4V Eli (ASTM F136)

Fixture Diameters (ø)	3.7, 4.2, 4.6, 5.0	3.7, 4.2, 4.6, 5.0	5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 7.8
Neck Lengths (mm)	2.0	2.0	2.0
Cuff Lengths (mm)	2.5, 3.5	1.5	1.0, 2.0, 3.0, 4.0
Implantable Lengths (mm)	7.0, 8.5, 10.0, 11.5, 13.0	7.0, 8.5, 10.0, 11.5, 13.0	7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0
Surface treatment	SLA	SLA	R.B.M
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Prosthetic Interface Connection	Square	Square	Internal Hex
Principle of Operation	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.
Substantial Equivalent Discussion	SD TL Implant System and SD TL Implant System(K242753) share the similar device characteristics with the primary predicate device, including indication for use, length, material, functions, structure, and production methods. Both devices are intended for use in partially or fully edentulous mandibles and maxillae. While subject device has cuff lengths of 2.5, 3.5 and primary predicate device has cuff lengths of 1.5. These dimensional differences are supported by the Reference Device(K212517), which covers a wider range of sizes, ensuring substantial. In conclusion, the additional details in the subject device do not affect its fundamental operation, intended use, or safety. The SD Tissue Level Implant is therefore substantially equivalent to both the Primary Predicate and Reference Device.		

2) SD Bone Level Fixture

	Subject Device	Primary Predicate
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Bone Level Fixture	NB 1 SA Implant System
510(k) Number	250280	K213506
Intended Use/ Indications for use	The SD TL 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. Abutments are indicated for screw-retained single restorations or cement-retained single of multi-unit restorations. SD TL Implant System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. All digitally-designed abutments are intended to be sent to an ARUM DENTISTRY validated milling center for manufacture.	The NB 1 SA 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. NB 1 SA Implant System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with diameters larger than 5mm are indicated for molar regions.
Material	Pure Titanium (ASTM F67)	Pure Titanium (ASTM F67)
Range of Diameters (ø)	6.48	3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5
Range of Lengths (mm)	7.0, 8.5, 10.0, 11.5	7.0, 8.5, 10, 11.5, 13.0
Surface treatment	SLA	SLA
Sterilization	Gamma Sterilization	Gamma Sterilization

Principle of Operation	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.
Substantial Equivalent Discussion	**1. Similarities** The SD Bone Level Fixture have similar device characteristics with the Primary predicate such as diameters, length, intended use, material, functions, general shape (Design), sterilization, structure and applied production method. **2. Differences** The SD Bone Level Fixture's diameter and is slightly different. However, except for the diameter, the length, intended use, material, functions and general shape (Design) are the same. The diameter dimension is range of the reference device encompasses the size of the subject device. Therefore, this difference doesn't impact substantial equivalence.	

3) Multi Angled Cylinder

	Subject Device	Primary Predicate	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	Guilin FiTeeth Medical Instrument Co., Ltd.	Oneday Biotech Co., Ltd.
Device Name	Multi Angled Cylinder	IM/ST Fixture System	Oneday Implant Abutment
510(k) Number	K250280	K212702	K231753
Intended Use/ Indications for use	The SD TL 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. Abutments are indicated for screw-retained single restorations or cement-retained single of multi-unit restorations. SD TL Implant System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. All digitally-designed abutments are intended to be sent to an ARUM DENTISTRY validated milling center for manufacture.	The IM/ST Fixture 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of singleor multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final ortemporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5mm are intended to be used in the molar region.
Material	Ti-6Al-4V Eli (ASTM F136)	Ti-6Al-4V Eli (ASTM F136)	Ti-6Al-4V Eli (ASTM F136)

Diameters (ø)	5.5	4.0, 5.0, 6.0	4.0, 4.5, 5.0, 5.5, 6.0, 7.0, 8.0
Lengths (mm)	9.5, 10.5	8.0	9.7, 10.7, 11.7, 12.7
Angulation	15	17	15, 25
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Multi Angled Cylinder is substantially equivalent in designs, dimensions, material, indications, technological characteristics with the identified primary predicate device. The Multi Angled Cylinder is similar in fundamental scientific technology to the predicate. The Indications for Use of the subject and primary predicate device are identical. **2. Differences** The differences between the subject device and reference device are the angulation. To support the angle, K231753 was added as reference device. Although, length is slightly different but it doesn't impact product's safety and effectiveness. Therefore, this difference doesn't impact substantial equivalence.		

4) Multi Digital Cylinder

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD TL Implant System	SD Implant System
510(k) No.	K250280	K241703
Diameters (ø)	5.5	5.5
Length (mm)	6.5, 7.5, 8.5, 9.5	5.5, 7.5
Metallic Component Material	Ti-6Al-4V ELI (ASTM F136)	Ti 6Al 4V ELI (Conforming to ASTM F136)
Superstructure Material	Zirconium Oxide (ZrO_2)	Zirconium Oxide (ZrO_2)
Surface Treatment	Machined	Machined
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Multi Digital Cylinder and the reference device are made of the same material and have a similar design. Both devices use Ti-6Al-4V ELI conforming to ASTM F136 and Zirconium Oxide as the superstructure material. They are machined and provided for end user sterilization. Additionally, both devices have the same function and indication for use, which supports their substantial equivalence. **2. Differences** The difference between subject device and reference device are dimension. These differences do not impact the product's fundamental functions and safety. Therefore, The Multi Digital Cylinder and Primary predicate are substantially equivalent.	

5) Multi Ti Cylinder

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD TL Implant System	SD Implant System
510(k) No.	K250280	K241703
Diameters (ø)	5.5	5.5
Length (mm)	6.5, 7.5, 8.5, 9.5	7.0
Metallic Component Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Superstructure Material	Zirconium Oxide (ZrO_2)	Zirconium Oxide (ZrO_2)
Surface Treatment	Machined	Machined
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Multi Ti Cylinder and reference device are made of the same material and have similar design. They have same function and indication for use statement. Both devices use Ti-6Al-4V ELI conforming to ASTM F136 and Zirconium Oxide as the superstructure material. They are machined and provided for end user sterilization. Additionally, both devices have the same function and indication for use, which supports their substantial equivalence. **2. Differences** The difference between subject device and reference device is dimension. These differences do not impact the product's fundamental functions and safety. Therefore, The Multi Ti Cylinder and reference device are substantially equivalent.	

6) Multi Healing Cap

	Subject Device	Reference Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.	MegaGen Implant Co., Ltd.
Device Name	SD TL Implant System	NB Mini Implant System	Healing Cap
510(k) No.	K250280	K240091	K233450
Range of Diameters (Ø)	5.5	4.2, 4.7, 5.7, 6.7, 7.7	4.9, 5.0, 5.5, 6.0, 6.1, 6.5, 6.8
Length (mm)	4.35, 5.85, 7.35	6.6 ~ 15.2	4.2 ~ 8.0
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Scanning feature	Machined	Machined	Machined, Anodizing
Sterilization	Gamma Sterilization	Gamma Sterilization	Non-sterile
Shelf life	5 Years	5 Years	-
Substantial Equivalent Discussion	**1. Similarities** The Multi Healing Cap has same indication for use, principle of operation, functions, diameter material and sterilization to the reference device, K240091 and K233450. **2. Differences** The difference between the subject and reference device is the dimension. There are slightly different dimensions. This dimensional difference doesn't affect device safety and effectiveness; therefore, it is substantial equivalent		

7) Healing Abutment

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD TL Implant System	NB Mini Implant System
510(k) No.	K250280	K240091
Range of Diameters (ø)	4.8, 5.7	4.2, 4.7, 5.7, 6.7, 7.7
Range of Cuff (mm)	1.5, 3.0, 4.5, 5.5	1.0, 2.0, 3.0, 4.0
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf life	5 Years	5 Years
Surface Treatment	Machined	Machined
Substantial Equivalent Discussion	**1. Similarities** The Healing Abutment has same indication for use, principle of operation, functions, diameter, material and sterilization to the reference device K240091. The intended use of the subject device as a healing abutment is designed to aid in soft tissue contouring during the healing period after implant placement, creating emergence profile for the final prosthesis is equivalent to the reference device K240091. **2. Differences** The difference between the subject and reference device is the dimension. The size range of the reference device encompasses the size of the subject device. This dimensional difference doesn't affect device safety and effectiveness; therefore, it is substantial equivalent	

8) Temporary Abutment

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	MegaGen Implant Co., Ltd.
Device Name	SD TL Implant System	Temporary Abutment
510(k) No.	K250280	K233450
Diameters (ø)	3.7, 4.0	3.5, 4.0, 4.5, 4.75
Post Height (mm)	7.0	8.0
Range of Cuff (mm)	1.0, 3.0	1.8, 2.0, 2.2, 2.8, 3.0, 3.2, 3.8, 4.0, 4.2,4.8, 5.0, 5.2
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Surface Treatment	Machined	TiN Coating
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Temporary Abutment have same design, function and indication for use statement and is made with same material as Ti-6Al-4V Eli conforming to ASTM F136 is generally used for cemented-retained restoration compared to that of the reference device, K233450. **2. Differences** The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety. Temporary Abutment and reference device are same indications for use; therefore, it is substantial equivalent.	

Performance Data

Non-clinical testing data submitted, referenced or relied on in this submission support demonstrating substantial equivalence.

Biocompatibility

Biocompatibility of Titanium Grade 4 (ASTM F67) and Ti-6Al-4V Eli (ASTM F136) demonstrated by the reference ARUM DENTISTRY submission, K213506, using the same materials and manufacturing processes as the subject device.

Biocompatibility testing according to ISO 10993-5 and ISO 10993-12 for the abutment (titanium base and bonded zirconia superstructure) by the reference from K240603, using the same materials and manufacturing processes as the subject device.

Sterilization validation

Sterilization validating testing has been performed in accordance with ISO 11137-1 and ISO 11137-2 to verify the sterility assurance level (10^{-6}) by selecting and substantiating a 25 kGy dose using method VDmax25. (Referenced from K213506);

End User Sterilization Validation Test Report on Abutments according to ANSI/AAMI ST79, ISO 17665-1, -2, ISO 11737-1,-2, and ISO 11138-1 referenced in K213506;

LAL endotoxin testing according to AAMI / ANSI ST72:2011/(R)2016;

Shelf-Life

The tests to validate the Shelf-Life of the device through the proposed Shelf-Life were conducted using the accelerated aging method in accordance to ASTM F1980 and test results validated 5 years Shelf-Life. Also, the following guidance documents were referred to

- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile. (referenced from K213506);

Non-Clinical Data

Mechanical performance testing was performed according to ISO 14801. For each compatible implant line, worst-case constructs were subjected to static compression and compression fatigue testing. Minor differences in the designs, dimensions, sizes, or compatible implant lines among the subject device, the primary predicate devices, and the reference devices do not affect substantial equivalence. These minor differences do not impact substantial equivalence because these differences are related to the compatible implant designs, or are mitigated by the mechanical performance testing.

Non-clinical performance data submitted to demonstrate substantial equivalence included:

- Static and fatigue testing according to ISO 14801.
- Scanning electron microscopy (SEM) and Energy dispersive X-ray spectroscopy (EDS) were conducted on the predicate K213506 and is leveraged from our own prior clearance for the identical SLA surface treatment and manufacturing.

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the primary predicate.

MR Environment Condition

Non-Clinical worst-case MRI review was performed to evaluated the SD TL Implant System devices in the MRI environment using scientific rationale and published literature (e.g., Terry O. Woods, Jana Delfino, & Sunder Rajan. (2019). Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices. *Journal of Testing and Evaluation* 49.2, 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

Conclusion

The directions for use statements are very similar and the list of compatible implant systems is also identical. Overall, the technical characteristics of the subject device are very similar to the predicate device. The subject device, predicate device, and reference device have the same intended use, similar technical characteristics, and are made of the same materials. The subject device, predicate device, and reference device have the same range of physical dimensions and must be sterilized using similar methods. The data included in this premarket notification demonstrate that the subject device is substantially equivalent to the predicate device listed above. Overall, the subject device is substantially equivalent to the predicate device.