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

February 24, 2025

Re: K241703
Trade/Device Name: SD Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 13, 2024
Received: January 28, 2025

Dear Choi Won-Yi:

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,

Sherrill Lathrop Blitzer

for 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)*
K241703

Device Name
SD Implant System

Indications for Use *(Describe)*
The SD Implant System is indicated for use in partially or fully edentulous mandibular and maxillary areas, 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. SD 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. The multi-unit abutments are designed for use in multi-unit restorations. They should be used in cases where multiple implants are placed to support a prosthetic dental restoration not suitable for single-unit restorations. All digitally designed abutments for use with Customized Abutment are intended to be manufactured at an ARUM DENTISTRY validated milling center. Smaller diameter implant bodies (i.e., 3.3mm and 3.7mm) are indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary

Submitter

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Device Information

- Trade Name: SD 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: 02/24/2025

Predicate Devices

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

Primary Predicate

- K213506, NB 1 SA Implant System by Arumdentistry Co., Ltd.

Reference Device

- K230725, NB Implant System by Arumdentistry Co., Ltd.
- K232560, Angled Abutment by Arumdentistry Co., Ltd.
- K223634, Customized Abutment by Arumdentistry Co., Ltd.
- K240091, NB Mini Implant System, by Arumdentistry Co., Ltd.
- K240603, Ti-Base & Master Fix by Arumdentistry Co., Ltd.
- K161416, Multi-unit Abutment Plus by Nobel Biocare AB
- K211090, ZENEX Implant System by Izenimplant Co., Ltd.
- K231753, Oneday Implant Abutment by Oneday Biotech Co., Ltd.
- K233450, MegaGen Dental Implant Abutment - Scan Healing Abutment; Temporary Abutment; Temporary Cylinder; Comfort Cap; Healing Cap; Healing Cap Screw; Milling Abutment; EZ Post Abutment; Extra EZ Post Abutment; EZ Post Cylinder; ZrGEN Abutment;

Multi-unit Abutment; Multi-unit Angled Abutment; AXA Abutment (Straight); AXA Abutment (Angled); Abutment Screw; Cylinder Screw; Crown Screw by MegaGen Implant Co., Ltd.

- K232268, STERI-OSS Implant System by Zeros Co., Ltd.
- K190837, Internal Hex Implant System by EBI Inc.

7.1. Device Description

7.1.1. General Description

SD Implant System consist of below:

Fixture

- SD Bone Level Fixture

Abutment

- Cover Screw
- Healing Abutment
- Scan Healing Abutment
- Scan Healing Abutment Screw
- Cemented Abutment
- Angled Abutment
- Master Fix
- Master Fix Screw
- Digital Abutment
- Temporary Abutment
- Multi Abutment
- Multi Angled Abutment
- Abutment Screw
- Multi Scan Healing Cap
- Multi Scan Healing Cap Screw
- Multi Master Fix
- Multi Master Fix Screw
- Multi Ti Cylinder
- Multi Digital Cylinder
- Multi Temporary Cylinder
- Multi Cylinder Screw

SD Implant System is consisted with Fixtures (SD Bone Level Fixture) and Abutments (Cover Screw, Healing Abutment, Scan Healing Abutment, Cemented Abutment, Angled Abutment, Master Fix, Digital Abutment, Temporary Abutment, Multi Abutment, Multi Angled Abutment,

Multi Scan Healing Cap, Multi Master Fix, Multi Ti Cylinder, Multi Digital Cylinder, Multi Temporary Cylinder)

Device Description

1) Fixtures

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.

An endosseous dental implant is a device made of a material Pure titanium (Conforming to ASTM F67) which will be placed in the alveolar bone to replace the function of missing tooth. The SD 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 internal hex and morse taper bevel. Smaller diameter implant bodies (i.e., 3.3mm and 3.7mm) are indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions.

The subject device abutments are not compatible with 3.8mm diameter implant bodies cleared in K213506 and K230725, nor with 3.2mm diameter implant bodies cleared in K240091.

2) Abutments

SD Implant System Abutment is compatible with the SD Implant Fixture and Some of the SD Implant System connections are compatible with NB 1 Compatible with SA Implant System, NB Implant System and NB Mini Implant System. (Cleared K213506, K230725, K240091)

SD Implant System Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures, Separate sets of abutments are presented for compatibility with each Fixture. Dental Abutments are similar to other commercially available products based on the intended use, technology used, claims, material composition employed and performance characteristics.

The Multi Abutments and Multi Angled Abutment are dental abutments intended to be placed onto osseointegrated dental implants to provide support for prosthetic superstructures at the gingival level. Multi Abutments are available as straight abutments, which have an integrated thread and can be placed directly onto the implant. Multi Angled Abutments are angled abutments, which can be attached to the implant with the corresponding abutment screw. The multi-unit abutments are intended for multi-unit restoration only.

Below are the abutment's features:

No.	Device Name	Uses	Surface treatment
1	Cover Screw	The Cover Screw is Intended to be temporarily connected to an endosseous dental implant to protect the implant connection interface during bone healing.	N/A
2	Healing Abutment	The Healing Abutment is designed to aid in soft tissue contouring during the healing period after implant placement, creating an emergence profile for the final prosthesis.	N/A
3	Scan Healing Abutment	The Scan Healing Abutments are designed to aid in soft tissue contouring during the healing period after implant placement, creating an emergence profile for the final prosthesis. They have the added design feature of machined marking for identification when taking an abutment level impression or an intraoral scan/digital impression. Identification and orientation information is captured in the intraoral scan or model scan.	N/A
4	Scan Healing Abutment Screw	The Scan Healing Abutment Screw is used for connect fixture and Scan Healing abutment.	N/A
5	Cemented Abutment	The Cemented Abutment is used as a support of prosthesis to restore the patient's chewing function.	N/A
6	Angled Abutment	The Angled Abutment is used as a support of prosthesis to restore the patient's chewing function.	N/A
7	Master Fix	The Master Fix is used as a support of prosthesis to restore the patient’s chewing function.	N/A
8	Master Fix Screw	The Master Fix Screw is used for connect fixture and Master Fix.	N/A
9	Digital Abutment	The Digital Abutment is used as a support of prosthesis to restore the patient’s chewing function.	N/A
10	Temporary Abutment	The Temporary Abutment is used as a support for provisional prosthesis to restore the patient’s chewing function. The Temporary Abutment is not to exceed 180 days	N/A
11	Multi Abutment	The Multi Abutment is a straight type, it is connected with fixture and it support prosthesis which restores tooth function.	N/A
12	Multi Angled Abutment	The Multi Angled Abutment is an angled type, it is connected with fixture and it support prosthesis which restores tooth function.	N/A

13	Abutment Screw	The Abutment Screw is used for connect fixture and abutment.	N/A
14	Multi Scan Healing Cap	The Multi Scan Healing Cap has the added feature of machined marking for easy identification when taking an abutment-level impression or an intraoral scan/digital impression from the healing abutment. Identification and orientation information is captured in the intraoral scan or model scan.	N/A
15	Multi Scan Healing Cap Screw	The Multi Scan Healing Cap Screw is used for connecting Abutment and Multi Scan Healing cap.	N/A
16	Multi Master Fix	The Multi Master Fix is used for connecting with Multi Abutment, Multi Angled Abutment to provide support for provisional restoration and used for fabricating the single and multiple abutments.	N/A
17	Multi Master Fix Screw	The Multi Master Fix Screw is used for connecting Abutment and Multi Master Fix Screw	N/A
18	Multi Ti Cylinder	The Ti Cylinder is used in conjunction with Multi Abutment, Multi Angled Abutment to provide support for provisional restoration and used for fabrication the single and multiple abutments.	N/A
19	Multi Digital Cylinder	The Digital Cylinder is used in conjunction with Multi Abutment, Multi Angled Abutment to provide support for provisional restoration and used for fabrication the single and multiple abutments.	N/A
20	Multi Temporary Cylinder	The Multi Temporary Cylinder is used in conjunction with Multi Abutment, Multi Angled Abutment to provide support for provisional restoration and used for fabricating the single and multiple abutments. The Multi Temporary Cylinder is not to exceed 180 days	N/A
21	Multi Cylinder Screw	The Multi Cylinder Screw is used for connecting Multi Abutment and Multi Angled Abutment to Multi Cylinder.	N/A

The Cover Screw, Healing Abutment, Scan Healing Abutment, Scan Healing Abutment Screw, Multi Scan Healing Cap and Multi Scan Healing Cap Screw are provided sterile by the manufacturer. All other abutments are provided non-sterile and should be sterilized by the end user before use. The multi-unit abutments included in this system are specifically intended to be used solely for multi-unit restorations. The SD Master Fix, multi Master Fix, Digital abutments, and multi Digital cylinder are composed of two-piece abutment that is a titanium base at the bottom and 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. All digitally designed custom abutments for use with SD Master Fix, multi Master Fix, Digital abutments, and multi Digital cylinder are to be sent to ARUM DENTISTRY validated milling center for manufacture. All superstructures are to be manufactured from zirconia (cleared K190112). Digitally designed CAD/CAM abutments must have a 0.5 mm minimum gingival height dimension. SD Master Fix, multi Master Fix, Digital abutments, and multi Digital cylinderare intended for single-unit or multi-unit restorations.

For the Master Fix, Multi Master Fix, Digital Abutment, Multi Digital Cylinder the design parameters for the CAD/CAM zirconia superstructure are:

Minimum wall thickness – 0.5 mm;
Minimum post height for single-unit restorations (length above the abutment collar / gingival height) – 4.5 mm;
Maximum gingival height – 5.0 mm;
Minimum gingival height – 1.5 mm;
Angulation - 0°
and All zirconia superstructures are for straight abutments only.

The Master Fix, Multi Master Fix, Digital Abutment, Multi Digital 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.

Raw material Zirconia Block
K190112, Non-Sterile Zirconia Block by FINE ADVANCED COMPOUND Co., Ltd.

Dental Cement
K193260, U-Cem Premium & MAZIC Cem by Vericom Co., Ltd.

The SD Implant System is intended for single use only. The Abutments are made of Ti-6Al-4V Eli (Conforming to ASTM F136) The SD Implant System connections compatible with NB 1 SA Implant System, NB Implant System and NB Mini Implant System

The dimension ranges of the subject device are below:

No.	Device Name	Dimension
1	SD Bone Level Fixture	Ø3.3, 3.7 (D) x 7.0, 8.5, 10.0, 11.5, 13.0 mm (L) Ø4.2, 4.6, 5.0 (D) x 7.0, 8.5, 10.0, 11.5, 13.0 mm (L)
2	Cover Screw	Ø3.0, 3.75 (D) x 5.4, 5.8, 6.4, 6.8 mm (L)
3	Healing Abutment	Ø4.2, 4.7, 5.7, 6.7 (D) x 1.5, 3.0, 4.5, 5.5 mm (G/H)
4	Scan Healing Abutment	Ø4.7, 5.7, 6.7 (D) x 1.5, 3.0, 4.5, 5.5 mm (G/H)
5	Scan Healing Abutment Screw	Ø2.49 (D) x 9.8 ~ 14.7 mm (Length)
6	Cemented Abutment	Ø4.0, 4.5, 5.5, 6.5 (D) x 5.5 mm (Post Height) x 1.5, 2.5, 3.5, 4.5, 5.5 (G/H)
7	Angled Abutment	Ø4.0, 4.5, 5.5 (D) x 8.0mm (Post Height) x 2.0, 4.0 mm (G/H) x 17° (angle)
8	Master Fix	Ø 4.0, 4.5, 5.5 (D) x 4.0mm (Post Height) x 1.5, 2.5, 3.5, 4.5, 5.5mm (G/H)
9	Master Fix Screw	Ø2.2, 2.25 (D) x 10.4, 10.75, 11.4, 11.75, 12.4, 12.75, 13.4, 13.75 14.4, 14.75 mm (Length)
10	Digital Abutment	Ø4.0, 4.5, 5.5 (D) x 4.0mm (Post Height) x 1.5, 2.5, 3.5mm (G/H)
11	Temporary Abutment	Ø3.7, 4.0 (D) x 7.0mm (Post Height) x 1.0, 3.0mm (G/H))
12	Multi Abutment	Ø4.8 (D) x 2.0mm (Post Height) x 1.5, 2.5, 3.5, 4.5 mm (G/H)
13	Multi Angled Abutment	Ø4.8 (D) x 2.5, 3.5, 4.5 mm (G/H) x 17, 30° (angle)
14	Abutment Screw	Ø2.0, 2.2, 2.3, 2.35 (D) x 6.4, 6.7, 6.8, 8.0, 8.5, 9.2 mm (L)
15	Multi Scan Healing Cap	Ø5.5 (D) x 4.78, 6.28 mm (Length)
16	Multi Scan Healing Cap Screw	Ø2.49 (D) x 4.8, 6.3 mm (Length)
17	Multi Master Fix	Ø5.5 (D) x 1.5, 2.5, 3.5 (G/H)
18	Multi Master Fix Screw	Ø2.25 (D) x 5.5, 6.5, 7.5 (Length)
19	Multi Ti Cylinder	Ø5.5 (D) x 5.5 mm (Post Height) x 1.5 mm (G/H)
20	Multi Digital Cylinder	Ø5.5 (D) x 4.0, 6.0 (Post Height) x 1.5 mm (G/H)
21	Multi Temporary Cylinder	Ø5.5 (D) x 7.0 mm (Post Height) X 1 mm (G/H)
22	Multi Cylinder Screw	Ø2.1 (D) x 4.5 mm (Length)

Tolerance of dimension shall be within ± 1% range.

The SD 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 4.0, 4.5, 5.0, 5.5, 6.0, 6.5
	K230725	NB Implant System	Ø 4.0, 4.5, 5.0, 5.5, 6.0, 6.5
	K240091	NB Mini Implant System	Ø 3.5

Indication for Use

The SD Implant System is indicated for use in partially or fully edentulous mandibular and maxillary areas, 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. SD 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. The multi-unit abutments are designed for use in multi-unit restorations. They should be used in cases where multiple implants are placed to support a prosthetic dental restoration not suitable for single-unit restorations. All digitally designed abutments for use with Customized Abutment are intended to be manufactured at an ARUM DENTISTRY validated milling center. Smaller diameter implant bodies (i.e., 3.3mm and 3.7mm) are indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions.

Materials

The Fixtures are fabricated from Pure Titanium (Conforming to ASTM F67)

All Abutments and Abutment Screws are fabricated from Ti-6Al-4V Eli (Conforming to ASTM F136).

Raw material Zirconia Block K190112, Non-Sterile Zirconia Block by FINE ADVANCED COMPOUND Co., Ltd.

7.2.1. Summaries of Technology Characteristics

1) SD Bone Level Fixture

	Subject Device	Primary Predicate	Reference Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.	EBI Inc.
Device Name	SD Implant System	NB 1 SA Implant System	NB Mini Implant System	Internal Hex Implant System
510(k) Number	N/A	K213506	K240091	K190837
Intended Use/ Indications for use	The SD Implant System is indicated for use in partially or fully edentulous mandibular and maxillary areas, 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. SD 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	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	The NB Mini Implant System is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The NB Mini Implant System is indicated also for immediate loading when good primary stability	The Internal Hex Implant System is intended for placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. For implant bodies Ø4.1 and greater, the Internal Hex Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implant bodies with a diameter less than Ø4.1 are intended for immediate loading when using a minimum of 4

	5mm are indicated for molar regions. The multi-unit abutments are designed for use in multi-unit restorations. They should be used in cases where multiple implants are placed to support a prosthetic dental restoration not suitable for single-unit restorations. All digitally designed abutments for use with Customized Abutment are intended to be manufactured at an ARUM DENTISTRY validated milling center. Smaller diameter implant bodies (i.e., 3.3mm and 3.7mm) are indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions.	are indicated for molar regions.	is achieved and with appropriate occlusal loading.	implants with length >8mm.
Material	Pure Titanium (ASTM F67)	Pure Titanium (ASTM F67)	Ti-6Al-4V Eli (ASTM F136)	Pure Titanium (ASTM F67)
Anti-Rotational Feature	Internal Hex	Internal Hex	Internal Hex	Internal Hex

Range of Diameters (ø)	3.3, 3.7, 4.2, 4.6, 5.0	3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5	3.2, 3.5	3.25 - 5.5
Range of Lengths (mm)	7.0, 8.5, 10.0, 11.5, 13.0	7.0, 8.5, 10, 11.5, 13.0	8.5, 10.0, 11.5, 13.0	7 - 18
Surface treatment	SLA	SLA	SLA	SLA
Sterilization	Gamma Sterilization	Gamma 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.	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.			

2) Cover Screw

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Implant System	NB Mini Implant System
510(k) Number	N/A	K240091
Range of Diameters (ø)	3.0, 3.75	2.8
Range of Lengths (mm)	5.4, 5.8, 6.4, 7.8	5.1, 5.8, 6.8, 7.8
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
Substantial Equivalent Discussion	**1. Similarities** The subject device is similar in intended use, fundamental scientific technology, principle of operation, design, technology, functions, sterilization and materials with the identified reference device. **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.	

3) Healing Abutment

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Implant System	NB 1 SA Implant System
510(k) No.	N/A	K240091
Range of Diameters (ø)	4.2, 4.7, 5.7, 6.7	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	

4) Scan Healing Abutment

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Implant System	NB Mini Implant System
510(k) No.	N/A	K240091
Range of Diameters (ø)	4.7, 5.7, 6.7	4.2 ~ 7.7
Range of Cuff (mm)	1.5, 3.0, 4.5, 5.5	1.3 ~ 9.4
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Scanning feature	Machined marking	Machined marking
Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf life	5 Years	5 Years
Substantial Equivalent Discussion	**1. Similarities** The Scan 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 scan healing abutment with scanning feature to transmit position and angulation data of implant when taking a digital impression using an intra-oral scanner 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.	

5) Scan Healing Abutment Screw

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Implant System	NB Mini Implant System
510(k) No.	N/A	K240091
Range of Diameters (ø)	2.49	2.49
Length (mm)	9.8 ~ 14.7	9.7 ~ 19.4
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Scanning feature	Machined marking	Machined marking
Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf life	5 Years	5 Years
Substantial Equivalent Discussion	**1. Similarities** The Scan Healing Abutment Screw 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 scan healing abutment screw is used for connect fixture and Scan Healing Abutment. **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.	

6) Cemented Abutment

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Implant System	NB 1 SA Implant System
510(k) No.	N/A	K213506
Diameters (Ø)	4.0, 4.5, 5.5, 6.5	4.5, 5.5, 6.5
Post Height (mm)	5.5	5.0, 5.5, 7.0
Range of Cuff (mm)	1.5, 2.5, 3.5, 4.5, 5.5	1.0, 2.0, 3.0, 4.0, 5.0, 6.0
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 subject device is similar in intended use, fundamental scientific technology, principle of operation, design, technology, functions, dimensions, and materials with the identified reference device, K213506. **2. Differences** The difference between the subject and reference device is the dimensions of the device. There are slightly different dimensions. However, the size range of the reference device encompasses the size of the subject device. It does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

7) Angled Abutment

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Implant System	Angled Abutment
510(k) No.	N/A	K232560
Diameters (ø)	4.0, 4.5, 5.5	4.0, 4.5, 5.0, 6.0
Post Height (mm)	8.0	8.0
Range of Cuff (mm)	2.0, 4.0	2.0, 4.0
Angulation (°)	17	17
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 Angled Abutment has 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, K232560. **2. Differences** Surface treatment between the proposed and predicated Angled Abutment is different. But proposed Angled Abutment and predicated Angled Abutment have common in design, function, indications for use, material, etc. therefore, the proposed Angled Abutment is substantially equivalent to the reference device, K232560	

8) Master Fix

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Implant System	Ti-Base & Master Fix
510(k) No.	N/A	K240603
Implant Body Diameter (Ø)	3.3 ~ 6.2	3.35
Diameter (Ø)	4.5, 5.5	3.5, 4.0, 5.0
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Surface Treatment	Machined	Machined
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Master Fix 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, K240603. **2. Differences** The minor difference with the reference device K240603 is slightly different dimension. These minor differences do not impact safety and effectiveness because these differences are related to the compatible implant design and are mitigated by the mechanical performing testing.	

9) Digital Abutment

	Subject Device	Reference Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	Zeros Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Implant System	STERI-OSS Implant System	NB 1 SA Implant System
510(k) No.	N/A	K232268	K213506
Diameters (ø)	4.0, 4.5, 5.5	4.0, 4.5, 5.0, 5.5, 6.0, 6.5	4.5, 5.5, 6.5
Post Height (mm)	4.0, 6.0	4.0, 5.5, 7.0	5.0, 5.5, 7.0
Range of Cuff (mm)	1.5, 2.5, 3.5	1.0, 2.0, 3.0, 4.0, 5.0, 6.0	1.0, 2.0, 3.0, 4.0, 5.0, 6.0
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)
Surface Treatment	Machined	Machined	TiN Coating
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Digital Abutment have similar 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, K213506. **2. Differences** The difference between the subject and reference device is the dimensions of the device. And added K232268 reference device, to support surface treatment. However, it does not affect device's fundamental functions and safety. Digital Abutment and reference device are same indications for use; therefore, it is substantial equivalent.		

10) Temporary Abutment

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	MegaGen Implant Co., Ltd.
Device Name	SD Implant System	Temporary Abutment
510(k) No.	N/A	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.	

11) Multi Abutment

	Subject Device	Primary Predicate
Manufacturer	ARUM DENTISTRY Co., Ltd.	Nobel Biocare AB
Device Name	SD Implant System	Multi-unit Abutment Plus
510(k) No.	N/A	K161416
Diameters (ø)	4.8	4.8
Range of Cuff (mm)	1.5, 2.5, 3.5, 4.5	1.5, 2.5, 3.5, 4.5
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Surface Treatment	Machined	Machined
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The multi abutment and primary predicate are made of the same material and have similar design. The size range of the primary predicate encompasses the size of the subject device. They have same design, function and indication for use statement and is made with same material as Ti-6Al-4V Eli conforming to ASTM F136 compared to that of the primary predicate, K161416. **2. Differences** The difference between subject device and primary predicate is design. These differences do not impact the product's fundamental functions and safety. Therefore, The Multi Abutment and Primary predicate are substantially equivalent.	

12) Multi Angled Abutment

	Subject Device	Primary Predicate
Manufacturer	ARUM DENTISTRY Co., Ltd.	Nobel Biocare AB
Device Name	SD Implant System	Multi-unit Abutment Plus
510(k) No.	N/A	K161416
Diameters (ø)	4.8	4.8
Range of Cuff (mm)	2.5, 3.5, 4.5	2.5, 3.5, 4.5
Angulation (°)	17, 30	17, 30
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Surface Treatment	Machined	Machined
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Multi Abutment and primary predicate are made of the same material and have similar design. The size range of the primary predicate encompasses the size of the subject device. They have same design, function and indication for use statement and is made with same material as Ti-6Al-4V Eli conforming to ASTM F136 compared to that of the primary predicate, K161416. **2. Differences** The difference between subject device and primary predicate is design. These differences do not impact the product's fundamental functions and safety. Therefore, The Multi Abutment and Primary predicate are substantially equivalent.	

13) SD Abutment Screw

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Implant System	NB 1 SA Implant System
510(k) No.	N/A	K213506
Diameters (ø)	2.0, 2.2, 2.3, 2.35	2.35
Length (mm)	6.4, 6.7, 6.8, 8.0, 8.5, 9.2	8.4
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Surface Treatment	Machined	Machined
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Abutment Screw and Reference Device are made of same material and have similar design. They have same design, function and indication for use statement and is made with same material as Ti-6Al-4V Eli conforming to ASTM F136 compared to that of the reference device, K213506. **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 Abutment Screw and Reference Device are substantially equivalent.	

14) Multi Scan Healing Cap

	Subject Device	Reference Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.	MegaGen Implant Co., Ltd.
Device Name	SD Implant System	NB Mini Implant System	Healing Cap
510(k) No.	N/A	K240091	K233450
Range of Diameters (Ø)	5.5	4.2 ~ 7.7	4.9, 5.0, 5.5, 6.0, 6.1, 6.5, 6.8
Length (mm)	4.78, 6.28	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 Scan Healing Cap has same indication for use, principle of operation, functions, diameter material and sterilization to the reference device, K240091 and K233450. The intended use of the subject device as a Scan Healing Abutment Cap with scanning feature to transmit position and angulation data of implant when taking a digital impression using an intra-oral scanner is equivalent to the reference device, K240091. **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. The Multi Scan Healing Cap is connected to the multi abutment and The Scan Healing Abutment is connected to the Implant.		

15) Multi Scan Healing Cap Screw

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Implant System	NB Mini Implant System
510(k) No.	N/A	K240091
Range of Diameters (ø)	2.49	2.49
Length (mm)	4.8, 6.3	9.7, 11.4, 11.7, 13.4, 13.7, 15.4, 15.7, 17.4, 17.7, 19.4
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Scanning feature	Machined	Machined
Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf life	5 Years	5 Years
Substantial Equivalent Discussion	**1. Similarities** The Multi Scan Healing Abutment Screw 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 Scan Healing abutment Screw with scanning feature to transmit position and angulation data of implant when taking a digital impression using an intra-oral scanner is equivalent to the reference device, K240091. **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.	

16) Multi Master Fix

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	SD Implant System	Ti-Base & Master Fix
510(k) No.	N/A	K240603
Diameters (ø)	5.5	3.35
Length (mm)	5.5, 6.7, 7.5	3.5, 4.0, 5.0
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Surface Treatment	Machined	Machined
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Multi Master Fix and reference device are made of the same material and have similar design. They have same design, function and indication for use statement and is made with same material as Ti-6Al-4V Eli conforming to ASTM F136 compared to that of the primary predicate, K240603. **2. Differences** The difference between subject device and primary predicate is dimension and design. These differences do not impact the product's fundamental functions and safety. Therefore, The Multi Master Fix and reference device are substantially equivalent.	

17) Multi Ti Cylinder

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	Oneday Biotech Co., Ltd.
Device Name	SD Implant System	Oneday Implant Abutment
510(k) No.	N/A	K231753
Diameters (ø)	5.5	4.8
Length (mm)	7.0	7.0
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti 6Al 4V ELI (Conforming to ASTM F136)
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 and is made with same material as Ti-6Al-4V Eli conforming to ASTM F136 compared to that of the reference device, K231753. **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 Abutment and reference device are substantially equivalent.	

18) Multi Digital Cylinder

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	Oneday Biotech Co., Ltd.
Device Name	SD Implant System	Oneday Implant Abutment
510(k) No.	N/A	K231753
Diameters (ø)	5.5	4.8
Length (mm)	5.5, 7.5	7.0
Material	Ti 6Al 4V ELI (Conforming to ASTM F136)	Ti 6Al 4V ELI (Conforming to ASTM F136)
Surface Treatment	Machined	Machined
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Multi Digital Cylinder and reference device are made of the same material and have similar design. They have same function and indication for use statement and is made with same material as Ti-6Al-4V Eli conforming to ASTM F136 compared to that of the primary predicate, K231753. **2. Differences** The difference between subject device and reference device are dimension and surface treatment. These differences do not impact the product's fundamental functions and safety. Therefore, The Multi Abutment and Primary predicate are substantially equivalent.	

19) Multi Temporary Cylinder

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	MegaGen Implant Co., Ltd.
Device Name	SD Implant System	Temporary Cylinder
510(k) No.	N/A	K233450
Range of Diameters (ø)	5.5	4.8, 4.9, 5.7
Post Height (mm)	7.0	8.5
Range of Cuff (mm)	1.0	3.0
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Surface Treatment	Machined	Machined
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Multi Temporary Cylinder has same indication for use, principle of operation, functions, material and sterilization to the reference device, 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.	

20) Multi Cylinder Screw

	Subject Device	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	MegaGen Implant Co., Ltd.
Device Name	SD Implant System	Cylinder Screw
510(k) No.	N/A	K233450
Range of Diameters (ø)	2.1	2.1
Length (mm)	4.5	4.2 ~ 4.65
Material	Ti-6Al-4V Eli (Conforming to ASTM F136)	Ti-6Al-4V Eli (Conforming to ASTM F136)
Surface Treatment	Machined	Machined
Sterilization	End User Sterilization	End User Sterilization
Substantial Equivalent Discussion	**1. Similarities** The Multi Cylinder Screw has same indication for use, principle of operation, functions, material and sterilization to the reference device, K233450. **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.	

Performance Data

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

Biocompatibility

Biocompatibility of 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.

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) was conducted to demonstrate a clean surface free of any chemical or particle residual from the surface.

- Energy dispersive X-ray spectroscopy (EDS) was conducted to demonstrate surface free of contaminants.

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 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 Indications for Use statements are highly similar, differing only in the list of compatible implant system systems. Overall, the Technological Characteristics of the Subject device are highly similar to the Predicate device. The Subject device, the Predicate device, and the Reference devices have the same intended use, have similar technological characteristics, and are made of the same materials. The Subject device, the Predicate, and Reference devices encompass the same range of physical dimensions, and are to be sterilized using similar methods. The data included in this premarket notification demonstrate substantial equivalence to the Predicate device listed above. Overall, the Subject device is substantially equivalent to the Predicate device.