January 6, 2024

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

Re: K242753
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: September 12, 2024
Received: December 6, 2024

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,

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.

Submission Number *(if known)*

K242753

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 Pre-Milled 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

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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: 01/06/2025

Predicate Devices

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

Primary Predicate

- K222778, Osstem Implant System by Osstem Implant CO., LTD.

Reference Device

- K153268, NR Line Implant System by Dentium Co., Ltd.
- K222792, SNUCONE Tissue Level Implant System by SNUCONE Co., Ltd.
- K223634, Customized Abutment by ARUM DENTISTRY Co., Ltd.

General Description

SD TL Implant System consist of below:

Fixture

- SD Tissue Level Fixture

Abutment

- Multi Pre-Milled Cylinder

Device Description

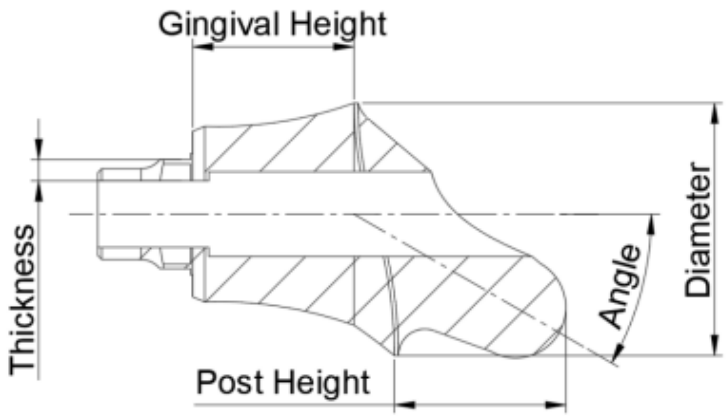
An endosseous dental implant is a device made of a material such as Pure Titanium (Conforming to ASTM F67) which will be placed in the alveolar bone to replace the function of the missing tooth. The SD TL Implant System consists of dental implants, abutments for use in one or two-stage dental implant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

The implant-abutment connection is tight and precise fitting with non-submerged external connection. 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 SD TL Implants are available with a gingival height of 1.5 mm.

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 Pre-Milled cylinders come in engaging and non-engaging types. All designed abutments are sent to an ARUM DENTISTRY validated milling center.

The diameters of Multi Pre-Milled Cylinder are 4.8 mm Square.

Patient-specific abutment design parameters:



Parameter	Min (mm)	10 Ø Max (mm)	14 Ø Max (mm)
Post Height for Single-Unit Restoration	4.0	13.0	13.0
Angle	0°	30°	30°
Wall Thickness	0.5	3.8	6.0
Diameter	Based on minimum wall thickness	9.9	13.9
Gingival Height	0.5	4.0	4.0

* Post height for single-unit restoration is defined as the cementable post measured above the gingival collar of the final abutment design

※ **When machined at an angle of above 0°**

- Post Height for Single-Unit Restoration: 4.25mm
- Wall Thickness:0.5mm
- Diameter: 6.25
- Gingival Height: 4.0mm

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)

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

Summaries of Technology Characteristics

1) SD Tissue Level Fixture

	Subject Device	Primary Predicate	Reference Device
Manufacturer	ARUM DENTISTRY Co., Ltd.	Osstem Implant CO., LTD.	SNUCONE Co., LTD.
Device Name	SD Tissue Level Fixture	SSIII SA Implant	EF Fixture for SNUCONE Tissue Level Implant System
510(k) Number	N/A	K222778	K222792
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 Pre-Milled Abutments are intended to be sent to an ARUM DENTISTRY validated milling center for manufacture.	The Osstem Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide Implant System is intended to be used in the molar region. Products with diameter of less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	SNUCONE Tissue Level 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, or overdenture restorations and terminal or intermediate Abutment support for fixed bridge work. Snucone 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.
3.7Material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)

Range of Diameters (ø)	3.7, 4.2, 4.6, 5.0	4.8, 6.0	3.7, 3.8, 4.1, 4.3, 4.8, 5.3, 5.5, 5.8
Range of Lengths (mm)	7.0, 8.5, 10.0, 11.5, 13.0	7.0, 8.5, 10.0, 11.5, 13.0, 15.0	7, 8, 9, 10, 11, 12, 13, 14
Surface treatment	SLA	SLA	Acid etching
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.
Substantial Equivalent Discussion	**Similarities** The SD Tissue Level Fixture and SSIII SA Implant share similar device characteristics with the Reference Device, including indication for use, length, material, functions, structure, and production method. Both devices are intended for use in partially or fully edentulous mandibles and maxillae. While the Primary Predicate device has diameters of 4.8 and 6.0, the subject device offers diameters of 3.7, 4.2, 4.6, and 5.0. These dimensional differences are supported by the Reference Device (K222792), which covers a wider range of sizes, ensuring substantial equivalence. The abutment intended use is consistent with standard practices and does not introduce new risks. Immediate loading is applicable under specific conditions; if these conditions are not met, delayed loading is used, which aligns with the Primary Predicate's intended use. The subject device's milling center ensures product quality and manufacturing control, without affecting the abutment's material, design, or function. In conclusion, the additional details in the subject device do not affect its fundamental operation, intended use, or safety. The SD TL Implant System is therefore substantially equivalent to both the Primary Predicate and Reference Device.		

2) Multi Pre-Milled Cylinder

<table>
<tr><th></th><th>Subject Device</th><th>Reference Device</th><th>Reference Device</th></tr>
<tr><td>Manufacturer</td><td>ARUM DENTISTRY Co., Ltd.</td><td>ARUM DENTISTRY Co., Ltd.</td><td>Dentium Co., Ltd.</td></tr>
<tr><td>Device Name</td><td>Multi Pre-Milled Cylinder</td><td>Customized Abutment</td><td>NR Line Implant System</td></tr>
<tr><td>510(k) No.</td><td>N/A</td><td>K223634</td><td>K153268</td></tr>
<tr><td>Intended Use/ Indications for use</td><td>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.</td><td>ARUM Dentistry’s Customized Abutments are intended for attachment to dental implants in order to provide support for customized prosthetic restorations. Customized Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. The Customized Abutment will be attached to a dental implant using the included ARUM Dentistry prosthetic screw.
Customized Abutments are compatible with the implant systems listed in the Compatibility Table:
<table>
<tr><th>Implant Platform compatibility</th><th>Restorative Platform diameter (mm)</th><th>Implant Body diameter (mm)</th></tr>
<tr><td>NB 1 SA Implant System</td><td>3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5</td><td>3.8, 4.0, 4.15, 4.25, 4.5, 5.0</td></tr>
</table>
All digitally-designed Customized Abutments are intended to be sent to an ARUM Dentistry-validated milling center for manufacture.</td><td>The NR Line Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient’s chewing function. NR Line Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.</td></tr>
<tr><td>Sterilization</td><td>Steam Sterilization by user (Provided Non-Sterile)</td><td>Steam Sterilization by user (Provided Non-Sterile)</td><td>Steam Sterilization by user (Provided Non-Sterile)</td></tr>
</table>

Type of Retention	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained
Diameter (mm)	CAD/CAM Patient-Specific Abutment: 4.2, 4.35, 4.6, 4.75, 5.0, 5.15, 6.2	CAD/CAM Patient-Specific Abutment: 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5	3.7, 4.3, 5.5, 6.5
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)
Connection type	Square	Internal Hex	Square
Surface Treatment	Machined	Machined	Machined
Substantial Equivalent Discussion	**1. Similarities** The Multi Pre-Milled Cylinder is substantially equivalent in designs, dimensions, material, indications, abutment seat, screw seat, anatomical site, and technological characteristics with the identified primary predicate device. The patient-specific abutment 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 connection type. To support the square connection, K153268 was added as reference device. Although, connection type is slightly different but it doesn't impact product's safety and effectiveness. Therefore, this difference doesn't impact substantial equivalence.		

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.

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 Indications for Use statements are highly similar, differing only in the list of compatible implant 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.