December 19, 2023

Arum Dentistry Co., Ltd.
Won-Yi Choi
Assistant Manager
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
REPUBLIC OF KOREA

Re: K232560
Trade/Device Name: Angled Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 21, 2023
Received: November 21, 2023

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232560

Device Name
Angled Abutment

Indications for Use *(Describe)*
Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crown, bridges, or over-dentures.

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.

510(k) Summary

Submitter

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Date prepared: December 14, 2023

Device Information

- Trade Name: Angled Abutment
- Common Name: Endosseous Dental Implant Abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Primary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3630
- Device Class: Class II
- Date Prepared: 11/20/2023

Predicate Devices

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

Primary Predicate

K182091, Osstem Abutment System by OSSTEM Implant Co., Ltd.

Reference Device

K213506, NB 1 SA Implant System by ARUM DENTISTRY Co., Ltd.

K230725, NB Implant System by ARUM DENTISTRY Co., Ltd.

General Description

Abutment

- Angled Abutment

The Angled Abutment is made from Ti-6Al-4V Eli (conforming to ASTM F136). Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crown, bridges, or over-dentures. The Angled Abutment has two types of connection (HEX and Non-HEX). The Angled Abutment connections compatible with NB 1 SA Implant System and NB Implant System. The Angled Abutment surfaces are partially TiN coated. Angled Abutments are supplied with an abutment screw previous cleared device as K213506.

The dimension ranges of the subject device are below:

No.	Device Name	Dimension
1	Angled Abutment	Ø4.5, 5.5 (D) x 8 mm (Post Height) x 17°
2	Abutment Screw (Cleared in K213506)	Ø 2.35 (D) x 8.4 mm (L)

Angled Abutment and Abutment Screw (Cleared in K213506) are provided non-sterile. The abutment should be sterilized before use by end user sterilization. These devices are intended for single use only.

The Angled Abutment is compatible with the following implant systems.

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

Indication for Use

Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crown, bridges, or over-dentures.

Materials:

No.	Component Name	Materials	Surface treatment
1	Angled Abutment	Ti-6Al-4V Eli of ASTM F136	TiN coating

2	Abutment Screw (Cleared in K213506)	Ti-6Al-4V Eli of ASTM F136	Non coating

Summaries of Technology Characteristics

1) Angled Abutment

	Subject Device	Primary Predicate
Manufacturer	ARUM DENTISTRY Co., Ltd.	OSSTEM Implant Co., Ltd.
Device Name	Angled Abutment	Osstem Abutment System
510(k) Number	N/A	K182091
Intended Use/ Indications for use	Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crown, bridges, or over-dentures.	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Design		
Material	Ti-6Al-4V Eli (ASTM F136)	Ti-6Al-4V Eli (ASTM F136)
Anti-Rotational Feature	Hex, Non-Hex	Hex, Non-Hex
Range of Diameters (ø)	4.5, 5.5	4.0, 4.5, 5.0, 6.0
Rang of Post (mm)	8	8
Angle (°)	17	17
Sterilization	Non-Sterilization	Non-Sterilization

Surface Treatment	TiN Coating	TiN Coating
Substantial Equivalent Discussion	**1. Similarities** The Angled Abutment has the same intended use for, technological characteristics to the K182091.The Angled Abutment have same device characteristics with the reference device predicate such as material, anti-rotational feature, range of post, angle, sterilization intended use, functions, general shape (Design), structure and applied production method. **2. Differences** Compared to the reference device predicate, the subject device's diameter is different. However, except for the diameters, range of lengths (post, angle, intended use, material, functions and general shape (Design) are the same. Although the diameters are slightly different but it doesn't impact product's safety and effectiveness because the Subject Device is included in the range of reference device predicate's diameters.	

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

The Angled Abutment delivered non-sterile to be end-user sterilized, the recommended sterilization has been validated according to ISO 17655-1 and to applicable recommendations in the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015". The predicate devices may be leveraged for the subject devices because of using the same materials, manufacturing methods, and sterilization procedures. The sterilization methods were leveraged from predicated K213506. The worst-case construct was tested, and results demonstrated equivalence to the predicate devices.

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 Angled Abutment 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. Overall, the Technological Characteristics of the Subject device are highly similar to the Predicate devices. The Subject device, the Predicate devices, 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 devices, 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 devices listed above. Overall, the Subject device is substantially equivalent to the Predicate devices.