September 19, 2022

Arum Dentistry Co., Ltd.
Bo-Yeon Lim
Assistant Manager
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
REPUBLIC OF KOREA

Re: K222131
Trade/Device Name: NB 1 SA Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 29, 2022
Received: August 29, 2022

Dear Bo-Yeon Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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
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)*
K222131

Device Name
NB 1 SA Implant System

Indications for Use *(Describe)*
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.

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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K222131

510(k) Summary

Submitter

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Device Information

- Trade Name: NB 1 SA Implant System
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: 08/29/2022

Predicate Devices:

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

Primary Predicate

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

General 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.

Fixture's surface 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	NB I Fixture	Ø 3.8 (D) x 8.5, 10, 11.5, and 13 mm (L)
		Ø 4.0, 4.5, 5.0 (D) x 7.0, 8.5, 10, 11.5, and 13 mm (L)
		Ø 5.5, 6.0, 6.5 (D) x 7.0, 8.5, 10, 11.5, and 13 mm (L)
2	Cover Screw	Ø3.6 (D) x 5.3, 6.0, 7.0, 8.0 mm (L)
3	Healing Abutment	Ø 4.2, 4.7, 5.7, 6.7, 7.7 (D) x 1.0, 2.0, 3.0, 4.0mm (Cuff Height)
4	Cemented Abutment	Ø 4.5, 5.5, 6.5 (D) x 5.0, 5.5, 7.0 mm (Post Height)
5	Abutment Screw	Ø 2.35 (D) x 8.4 mm(L)

Tolerance of dimension shall be within ±1% range.

Fixtures are packaged with cover screw and provided sterile by gamma radiation. Abutments are packaged with abutment screw and provided non-sterile, should be sterilized before use. These devices are intended for single use only.

Indication for Use

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.

Materials:

The Fixtures are fabricated from Pure titanium (Conforming to ASTM F67).
Abutment and cover screw are fabricated from Ti-6Al-4V (Conforming to ASTM F136).

Summaries of Technology Characteristics:

1) NB I Fixture

	Subject Device	Primary Predicate
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	NB 1 SA Implant System	NB 1 SA Implant System
Product Name	NB I Fixture	ARUM NB 1 SA Fixture
510(k) Number	NA	K213506
Device classification	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Product Code	DZE	DZE
Regulation Number	872.3640	872.3640
Indications for use	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.	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.
Design		
Material	TI CP4 of ASTM F67	TI CP4 of ASTM F67

Anti-Rotational Feature	Internal Hex	Internal Hex
Range of Diameters (Ø)	3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5	3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5
Range of Lengths (mm)	7.0, 8.5, 10, 11.5, 13.0	7.0, 8.5, 10, 11.5, 13.0
Surface treatment	SLA	SLA
Gamma Sterilization	Yes	Yes

Similarities

The NB I Fixture has same fundamental scientific technology, principle of operation, general shape (design), functions, diameter and material to the predicate.

Differences

Only change the product name. Therefore, it doesn't impact product's substantial equivalence.

2) Cover Screw

	Subject Device	Primary Predicate
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	NB 1 SA Implant System	NB 1 SA Implant System
Product Name	Cover Screw	ARUM NB Cover Screw
510(k) No.	N/A	K213506
Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Design		
Range of Diameters (Ø)	3.6	3.6
Range of Lengths (mm)	5.3, 6.0, 7.0, 8.0	5.3, 6.0, 7.0, 8.0
Surface treatment	Non-Anodizing	Non-Anodizing
Gamma Sterilization	Yes	Yes

Similarities

The Cover Screw has same fundamental scientific technology, principle of operation, general shape (design), functions, diameter and material to the predicate.

Differences

Only change the product name. Therefore, it doesn't impact product's substantial equivalence.

3) Healing Abutment

	Subject Device	Primary Predicate
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	NB 1 SA Implant System	NB 1 SA Implant System
Product Name	Healing Abutment	ARUM NB Healing Abutment
510(k) No.	N/A	K213506
Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Design		
Range of Diameters (Ø)	4.2, 4.7, 5.7, 6.7, 7.7	4.2, 4.7, 5.7, 6.7, 7.7
Range of Lengths (mm)	5.3, 6.0, 7.0, 8.0	5.3, 6.0, 7.0, 8.0
Range of Cuff (Ø)	1.0, 2.0, 3.0, 4.0	1.0, 2.0, 3.0, 4.0
Gamma Sterilization	Yes	Yes
Surface Treatment	N/A	N/A
Sterilization	End User Sterilization	End User Sterilization

Similarities

The Healing Abutment has same fundamental scientific technology, principle of operation, general shape (design), functions, diameter and material to the predicate.

Differences

Compared to the Primary predicate, the subject devices have screw hole and changed the product name. However, except for the screw hole, the diameter, length, intended use, material, functions and general shape (Design) are the same. Therefore, this difference doesn't impact substantial equivalence.

4) Cemented Abutment

	Subject Device	Primary Predicate
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	NB 1 SA Implant System	NB 1 SA Implant System
Product Name	Cemented Abutment	ARUM Cemented Abutment
510(k) No.	N/A	K213506
Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Design		
Range of Diameters (mm)	4.5, 5.5, 6.5	4.5, 5.5, 6.5
Range of Lengths (mm)	5.3, 6.0, 7.0, 8.0	5.3, 6.0, 7.0, 8.0
Range of Post (mm)	5.0, 5.5, 7.0	5.0, 5.5, 7.0
Gamma Sterilization	Yes	Yes
Surface Treatment	N/A	N/A
Sterilization	End User Sterilization	End User Sterilization

Similarities

The Cemented Abutment has same fundamental scientific technology, principle of operation, general shape (design), functions, diameter and material to the predicate.

Differences

Compared to the Primary predicate, only change the product name and code. Therefore, it doesn't impact product's substantial equivalence.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic. NB 1 SA Implant System devices in the MRI environment using scientific rationale and published literature (e.g., *Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795).*, based on the entire system including all variations (all compatible implant bodied, 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.

Non-Clinical Data

No need to perform any non-clinical testing for the subject device since the subject device and predicate device are substantially equivalent in indications, fundamental technology, material and design.

Although the dimensions are slightly different, it doesn't impact product's safety and effectiveness because the predicate device is the worst case based on the product's dimensional comparison analysis provided.

Conclusion

The comparison between the target device and the predicate device shows that general information, including dimensions, fundamental designs and material information are identical. Therefore, the subject device is substantially equivalent to the predicate device.