July 1, 2023

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

Re: K230725
Trade/Device Name: NB Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 7, 2023
Received: April 7, 2023

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 -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)*
K230725

Device Name
NB Implant System

Indications for Use *(Describe)*
The NB 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 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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K230725

510(k) Summary

Submitter

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Device Information

- Trade Name: NB 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: 06/19/2023

Predicate Devices

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

Primary Predicate

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

Reference Device

- K173374, TSV BellaTek Encode Healing Abutment by Biomet 3i.
- K182448, Healing Abutment for AnyRidge Octa 1 Implant System by MegaGen Implant Co., Ltd.

General Description

The purpose of this submission is to expand the fixtures to include a new external thread design, and prosthetics to include the Scan Healing Abutments. The fixtures and abutments in this system are below:

Fixture

- NB II Fixture

Abutment

- Scan Healing Abutment

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 NB Implant System consists of dental implants, abutments for use in one or two-stage dental implant placement and restorations.

The implant-abutment connection is internal hex and morse taper bevel. 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 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.

The dimension ranges of the subject device are below:

No.	Device Name	Dimension
1	NB II Fixture	Ø 4.0 (D) x 7.0, 8.5, 10, 11.5, 13 mm (L) Ø 4.5 (D) x 7.0, 8.5, 10, 11.5, 13 mm (L) Ø 5.0 (D) x 7.0, 8.5, 10, 11.5, 13 mm (L) Ø 5.5 (D) x 7.0, 8.5, 10, 11.5, 13 mm (L) Ø 6.0 (D) x 7.0, 8.5, 10, 11.5, 13 mm (L) Ø 6.5 (D) x 7.0, 8.5, 10, 11.5, 13 mm (L)

Fixtures are provided sterile by gamma radiation.

No.	Device Name	Dimension
1	Scan Healing Abutment	Ø4.7, 5.7, 6.7, 7.7 (D) x 1.3, 3.3, 5.3, 7.3, 9.3 mm (Cuff)
2	Scan Healing Abutment Screw	Ø2.49 (D) x 9.7, 11.7, 13.7, 15.7, 17.7 mm (L)

Scan Healing Abutment is provided non-sterile. The abutment should be sterilized before use by end user sterilization. These devices are intended for single use only.

Indication for Use

The NB 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 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 Abutment Screw are fabricated from Ti-6Al-4V Eli (Conforming to ASTM F136).

Summaries of Technology Characteristics

1) NB II Fixture

	Subject Device	Primary Predicate
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.
Device Name	NB Implant System	NB 1 SA Implant System
510(k) Number	N/A	K213506
Intended Use/ Indications for use	The NB 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 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.
Material	Pure Titanium (ASTM F67)	Pure Titanium (ASTM F67)
Anti-Rotational Feature	Internal Hex	Internal Hex
Range of Diameters (ø)	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
Sterilization	Gamma Sterilization	Gamma Sterilization
Principle of Operation	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.

Substantial Equivalent Discussion	**1. Similarities** The NB II Fixture have same device characteristics with the Primary predicate such as diameters, length, intended use, material, functions, general shape (Design), structure and applied production method. **2. Differences** Compared to the Primary predicate, the subject device's cutting-edge is longer than the Primary predicate. However, except for the cutting-edge, the diameters, length, intended use, material, functions and general shape (Design) are the same. This function of the cutting-edge is self-tapping by creating a screw path. Therefore, this difference doesn't impact substantial equivalence.

2) Scan Healing Abutment

	Subject Device	Primary Predicate	Reference Device	
Manufacturer	ARUM DENTISTRY Co., Ltd.	ARUM DENTISTRY Co., Ltd.	Biomet 3i	MegaGen Implant Co., Ltd.
Device Name	Scan Healing Abutment	Healing Abutment	TSV BellaTek Encode Healing Abutments	Healing Abutment for AnyRidge Octa 1 Implant System
510(k) No.	N/A	K213506	K173374	K182448
Material	Ti-6Al-4V Eli	Ti-6Al-4V Eli	Ti-6Al-4V Eli	Ti-6Al-4V Eli
Intended use	It is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the Abutment, Cover screw is removed.	It is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture. When inserting the Abutment, Cover screw is removed.	The TSVTM BellaTek® Encode® Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for acceptance of a final abutment and restoration.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: - Delayed loading. - Immediate loading when good primary

				stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.
Range of Diameters (Ø)	4.2 ~ 7.7	4.2 ~ 7.7	3.8 ~ 6.8	3.2 ~ 7.2
Range of Cuff (Ø)	1.3 ~ 9.4	1.0 ~ 4.0	3.0, 5.0, 7.0	2.5 ~ 9.5
Sterilization	Non-Sterilization	Non-Sterilization	Gamma Sterilization	Gamma Sterilization
Scanning feature	Machined marking	-	Machined marking	-
Surface Treatment	Non-Anodizing	Anodizing, Non-Anodizing	Anodizing	Anodizing
Substantial Equivalent Discussion	**1. Similarities** The Scan Healing Abutment has same indication for use, principle of operation, functions, diameter and material to the predicate K213506. The intended use of the subject device as a 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 predicate K173374. **2. Differences** There are slightly different dimensions. To support cuffs, K182448 were added. Therefore, this dimensional difference doesn't affect device safety and effectiveness.			

Performance Data

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

Biocompatibility

Biocompatibility of TI CP4 (ASTM F67) and Ti-6Al-4V Eli (ASTM F136) demonstrated by the reference ARUM DENTISTRY submission, K213506, using the same materials and manufacturing processes as the subject device.

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);

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

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 K21350;

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

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.

MR Environment Condition

Non-Clinical worst-case MRI review was performed to evaluated the NB 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.