April 6, 2022

Arumdentistry Co., Ltd.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K213506
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: March 4, 2022
Received: March 7, 2022

Dear April Lee:

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)*

K213506

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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510(K) Summary

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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: 04/06/2022

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

Primary Predicate

- K181138, IS-III active System by Neobiotech Co., Ltd.

Reference Device

- K150060, J2A Dental Implant System manufactured by KJ Meditech Co., Ltd.
- K172100, URIS Implant System by Truabutment Inc.
- K193425, Pre-Milled Blank by Arumdentistry Co., Ltd.

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.

Device Description:
The NB 1 SA Implant System is composed of ARUM NB 1 SA Fixture, ARUM NB Cover Screw, ARUM NB Healing Abutment, ARUM Cemented Abutment (Hex, Non-Hex), and Abutment screw. ARUM NB 1 SA Fixture is a thread type implant body made of TI CP4 according to ASTM F67 which will be placed in the alveolar bone to replace the function of the missing tooth.
The surface of the fixture is treated with SLA (Sandblasted with Large grit and Acid-etching). The fixture is placed in the anterior or posterior site of maxillary or mandibular jawbone considering bone quality and bone quantity and it is connected with dental prostheses.

The dimensions of the subject device are as following:

No.	Device Name	Dimension Ranges
1	ARUM NB 1 SA 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	ARUM NB Cover Screw	Ø 3.6 (D) x 5.3, 6, 7, 8 mm (L)
3	ARUM NB 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	ARUM Cemented Abutment_Hex	Ø 4.5, 5.5, 6.5 (D) x 5.0, 5.5, 7.0 mm (Post Height)
	ARUM Cemented Abutment_Non Hex	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.

The Abutments have below featured:

Name	Uses	Surface	Connection
ARUM NB Cover Screw	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	Non	Screw Retained
ARUM NB Healing Abutment	Used to formation appropriate gingival shape during the soft tissue healing period combined with implant	Non	Screw Retained
ARUM Cemented Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	TiN Coating	Internal Hex, Non-hex
Abutment Screw	Abutment Screw is used to connect an abutment to the fixture.	Non	Screw Retained

ARUM NB 1 SA Fixture and ARUM NB Cover Screw are provided sterilized. And the other Abutments are provided non-sterilized.
ARUM NB 1 SA Fixture is enclosed with ARUM NB Cover Screw in a packing. ARUM Cemented abutment is enclosed with Abutment Screw in a packing.

Materials:

- The fixtures are fabricated from Pure titanium of ASTM F67
- ARUM Cemented abutment, abutment screw, Healing Abutment, and cover screw are fabricated from Ti-6Al-4V of ASTM F136

Summaries of Technological Characteristics & Substantial Equivalence Discussion

1) ARUM NB 1 SA Fixture

	Subject Device	Primary Predicate	Reference Device
Company	ARUMDENTISTRY Co., Ltd.	Neobiotech Co., Ltd	KJ Meditech Co., Ltd.
Device Name	NB 1 SA Implant System	IS-III active System	J2A Dental Implant System
510(k) Number	K213506	K181138	K150060
Device Classification	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Product Code	DZE	DZE	DZE
Regulation Number	872.3640	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 IS-III active 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. IS-III active 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 J2A Dental 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. The J2A Dental Implant System is for single and two stage surgical procedures. The system is intended for delayed loading.
Material	TI CP4 of ASTM F67	TI CP4 of ASTM F67	Ti-6Al-4V ELI of ASTM F136
Design			
Anti-Rotational Feature	Internal Hex	Internal Hex	Internal Hex
Diameters(Ø)	3.8/4.0/4.5/5.0/5.5/6.0/6.5	3.5/4.0/4.5/5.0/5.5/6.0/7.0	3.75/4.0/4.3/4.5/5.0/5.5/6.0
Lengths(mm)	7.0/ 8.5/ 10/ 11.5/ 13.0	7.3/8.5/l0.0/l1.5/13.0/15.0	7.0/8.5/l0.0/l1.5/13.0/15.0
Surface Treatment	SLA	SLA	RBM

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.
Similarities	The NB 1 SA Implant System has same device characteristics with the Primary predicate device, IS-III active System(K181138) such as intended use, material, functions, surface treatment, general shape (Design), structure, anti-rotational feature, principle operation and applied production method.		
Differences	The differences between the subject device and the primary predicate device are the product design and dimensional range. The design difference doesn't affect product's fundamental function. To support the dimensional differences such as fixture with Ø4.0 X 7.0mm, we selected K150060 as the reference device, which covers the subject device's dimensional range. Therefore, it is substantially equivalent.		

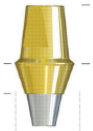
2) ARUM NB Cover Screw

	Subject Device	Primary Predicate
Company	ARUMDENTISTRY Co., Ltd.	Neobiotech Co., Ltd
Device Name	NB 1 SA Implant System	IS-III active System
510(k) Number	K213506	K181138
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters(Ø)	3.6	3.45/3.6
Lengths(mm)	5.3, 6, 7, 8 mm (L)	5.85/6.85/7.45/ 6.4/7.4/8.0/
Surface Treatment	Non-Anodizing	Anodizing/ Non-Anodizing,
Sterilization	Gamma Sterilization	Gamma Sterilization
Principle of Operation	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.
Similarities	The subject device has same intended use, material, functions, principle of operation, shelf life and similar design and dimensions.	
Differences	There are slightly different designs and dimension. These differences do not affect product's fundamental function; therefore, it is substantial equivalent.	

3) ARUM NB Healing Abutment

	Subject Device	Primary Predicate	Reference Device
Company	ARUMDENTISTRY Co., Ltd.	Neobiotech Co., Ltd	TruAbutment Korea Co., Ltd.
Device Name	NB 1 SA Implant System	IS-III active System	URIS OMNI System
510(k) Number	K213506	K181138	K172100
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI (ASTM F136)
Design			
Diameters (Ø)	4.2/4.7/5.7/6.7/7.7	4.0/4.5/4.8/5.5/6.0/6.8/8.0/9.0	4.0/4.5/5.5/6.5/7.5mm
Cuff height (mm)	1.0,2.0, 3.0, 4.0mm	2.3/2.8/3.3/3.8/4.3/4.8/5.3/5.8 /6.3/6.8/7.8/	1.0mm~5.0mm
Surface Treatment	N/A	N/A	Anodizing (Yellow, Green)
Sterilization	Non-sterile	Gamma Sterilization	Non-sterile
Principle of Operation	This product is healing Abutment to formation appropriate gingival shape during the soft tissue healing period combined with implant. This product should be removed when the superstructure is set up.	This product is healing Abutment to formation appropriate gingival shape during the soft tissue healing period combined with implant. This product should be removed when the superstructure is set up.	This product is healing Abutment to formation appropriate gingival shape during the soft tissue healing period combined with implant. This product should be removed when the superstructure is set up.
Similarities	The subject device has same intended use, material, functions, principle of operation, and similar design and dimensions.		
Differences	The differences between the subject device and the primary predicate device are the sterilization, dimensions and design. To support the difference of the sterilization, K172100 was added and the differences of design and dimensions do not affect product's fundamental function, therefore, it is substantially equivalent.		

4) ARUM Cemented Abutment

	Subject Device		Primary Predicate Device		
Company	ARUMDENTISTRY Co., Ltd.		Neobiotech Co., Ltd		
Device Name	NB 1 SA Implant System		IS-III active System		
510(k) Number	K213506		K181138		
Material	Ti-6Al-4V ELI of ASTM F136		Ti-6Al-4V ELI of ASTM F136		
Design					
	Hex	Non-Hex	Hex	Non-Hex	SCRP
Diameters (⌀)	4.5 / 5.5 / 6.5		4.5/5.2/5.7/6.5		
Post height (mm)	5.0/ 5.5 / 7.0		4.0/4.5/5.5/7.0/8.0		
Surface Treatment	TiN-Coating		TiN-Coating		
Principle of Operation	It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.		It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.		
Similarities	The subject and primary predicate have same indications for use, functions, materials, surface treatment, and general shape (design) as the primary predicate.				
Differences	The design of the devices is slightly different, but it doesn't affect device's fundamental functions; therefore, it is substantial equivalent.				

5) Abutment Screw

	Subject Device	Primary Predicate
Company	ARUMDENTISTRY Co., Ltd.	Neobiotech Co., Ltd
Device Name	NB 1 SA Implant System	IS-III active System
510(k) Number	K213506	K181138
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters (Ø)	2.35	2.3
Length (mm)	8.4	8.8/8.3
Surface Treatment	N/A	N/A
Principle of Operation	This product is a screw for connected with Abutment and fixture.	This product is a screw for connected with Abutment and fixture.
Similarities	The subject and primary predicate have same indications for use, functions, materials, surface treatment, general shape (design) and diameters.	
Differences	The design of the devices is slightly different, but it doesn't affect device's fundamental functions; therefore, it is substantial equivalent.	

Non-Clinical Test Data

Below tests were performed on subject device:

- Gamma Sterilization Validation Test on Fixtures according to ISO 11137-1,2,3
- Shelf-Life Test on Fixtures according to ASTM F1980
- Biocompatibility testing on fixtures according to ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2007, ISO 10993-10:2010 and ISO 10993-11:2006
- Biocompatibility testing on TiN Coating Abutments according to ISO 10993-1:2009, ISO 10993-5:2009 and ISO 10993-10:2010
- LAL endotoxin testing according to AAMI / ANSI ST72:2011/(R)2016

Below tests were performed for predicate device, K193425 and leveraged for the subject device:

- 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 K193425
- Biocompatibility testing on Abutments made with Ti-6Al-4V ELI according to ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2007, ISO 10993-10:2010 and ISO 10993-11:2006 referenced in K193425

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

The surface modification information such as surface roughness, surface composition analysis, and SEM imaging with SLA (Sandblasted with Large-grit and Acid-etching) for fixtures was provided.

For devices delivered sterile (ARUM NB 1 SA Fixture and Cover Screw) - a sterility assurance level (SAL) of 10^{-6} have been validated in accordance with ISO 11137-1:2006, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

Shelf Life Testing was performed in accordance with ASTM F1980, Standard Guide for Accelerated Aging of Sterile Medical Device Packages. The worst-case construct was tested, and results demonstrated equivalence to the predicate devices. The shelf life for devices provided sterile is 5 years. The devices will not be marketed as non-pyrogenic.

For all other subject devices delivered non-sterile to be end-user sterilized, the recommended sterilization has been validated according to ISO 17665-1 and ISO 17665-2 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 worst-case construct was tested, and results demonstrated equivalence to the predicate device.

Biocompatibility Testing was performed according to ISO 10993-1:2009, "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,*" and to the FDA Guidance document, "*Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff"*, Document issued on: June 16, 2016", for each of the subject devices.

The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion

The documentation submitted in this premarket notification demonstrates the NB 1 SA Implant System is substantially equivalent to the primary predicate and reference devices.