July 23, 2021

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

Re: K210903
Trade/Device Name: IS Multi Unit Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 21, 2021
Received: April 26, 2021

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)*
K210903

Device Name
IS Multi Unit Abutment System

Indications for Use *(Describe)*
IS Multi Unit Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as bridges.

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)

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510(k) Summary

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Device Information

- Trade Name: IS Multi Unit Abutment System
- Common Name: Endosseous Dental Implant Abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3630
- Device Class: Class II
- Date Prepared: 07/22/2021

Predicate Devices:

Primary Predicate

- K161689, OSSTEM Implant System-Abutment by Osstem Implant Co.,Ltd.

Reference Devices

- K120530, DENTIN Dental Implant System by Dentin Implant Technologies Ltd.
- K180282, MIS Internal Hex Dental Implant System by MIS Implant Technologies Ltd.
- K181138, IS-III active System by Neobiotech Co., Ltd.
- K182091, Osstem Abutment System by Osstem Implant Co.,Ltd.
- K182194, UV Active Implant System by DIO Corporation

Indications for Use:

IS Multi Unit Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as bridges.

Device Description

IS Multi Unit Abutments are premanufactured dental implant abutments directly connected to the endosseous dental implant with internal hex connection for restorations (multiple tooth). IS Multi Unit Abutment System is made of Titanium ELI according to ASTM F136.

IS Multi Unit Abutment System is composed of IS Multi Unit Abutment, IS Multi Unit Angled Abutment, Multi Unit Abutment Cylinder, Multi Unit Healing Cap, Multi Unit Temporary Cylinder, IS Multi Unit Angled Abutment Screw and Cylinder Screw.

All Multi-Unit Abutments (Straight/Angled) are intended only for multi-unit loaded restoration.

The dimensions of abutments are as following:

Name	Diameter (Ø)	Cuff(mm)	Length(mm)	Angulation
IS Multi Unit Abutment	⌀ 4.8	1.0/2.0/3.0/4.0/5.0/6.0	-	0º
IS Multi Unit Angled Abutment	⌀ 4.8	1.0/2.0/3.0/4.0		17 º,30 º
Multi Unit Abutment Cylinder	⌀ 4.8	-	5.0	0º
Multi Unit Healing Cap	⌀ 4.8	-	4.1	0º
Multi Unit Temporary Cylinder	⌀ 4.8/6.0	-	11.0	0º
IS Multi Unit Angled Abutment Screw	⌀2.3	-	8.3	0º
Cylinder Screw	⌀2.3	-	4.1	0º

The tolerance of dimension shall be within ± 1% range.

The IS Multi Unit Abutment System is compatible with following implant system:

K number	System Name	Diameter (Ø)	Length(mm)
K181138	IS-III active System	Ø 4.0/4.5/5.0/5.5	7.3/8.5/10.0/11.5/13.0/15.0
		Ø 6.0/7.0	7.3/8.5/10.0/11.5/13.0
K120503	CMI Implant IS II active	Ø 4.0/4.5/5.0/5.5/6.0/7.0/8.0	7.3/8.5/10.0/11.5/13.0/15.0

The features of each abutment are as following:

Name	Uses	Surface Treatment	Connection
IS Multi Unit Abutment	It is connected with Fixture and it supports prosthesis which restores tooth function.	N/A	Screw Retained
IS Multi Unit Angled Abutment		N/A	Hex, Non-Hex,
Multi Unit Abutment Cylinder	It is connected with Multi Unit Abutment (Straight/Angled) in order to cement final prosthesis.	N/A	Non-Hex
Multi Unit Healing Cap	It is connected with Multi Unit Abutment (Straight/ Angled type) in order to protect Multi Unit Abutment (Straight/Angled) and inner hole during the healing period.	N/A	Screw Retained
Multi Unit Temporary Cylinder	It is connected with Multi Unit Abutment (Straight/ Angled) and it supports prosthesis which restores tooth function as a temporary dental prosthesis.	N/A	Non-Hex
IS Multi Unit Angled Abutment Screw	It is used to fix Multi Unit Angled Abutment at the top of Fixture.	N/A	Screw Retained

Cylinder Screw	It is used to fix Multi Unit Abutment Cylinder or Multi Unit Temporary Cylinder at the top of Multi Unit Abutment (Straight/ Angled).	N/A	Screw Retained

Multi Unit Healing Cap is supplied sterile, and intended for singled use. Other Multi Unit components are supplied non sterile, to be steam sterilized by the user according to the labeling, and intended for single use.
IS Multi Unit Angled Abutment, Multi Unit Temporary Cylinder, Multi Unit Abutment Cylinder are provided with IS Multi Unit Abutment Screw or Cylinder Screw in packing.
And IS Multi Unit Abutment and Multi Unit Healing Cap have built in screw as an integral system.
All of above products including enclosed product are packed separately for convenience.

Materials:
All subject devices are made of Titanium ELI of ASTM F136.

Summaries of Technological Characteristics:
1) IS Multi Unit Abutment

	Subject Device	Primary Predicate Device	Reference Device
Company	Neobiotech Co., Ltd	Osstem Implant Co., Ltd.	Dentin Implants Technologies Ltd.
Device Name	IS Multi Unit Abutment System	OSSTEM Implant System-Abutment	DENTIN Dental Implant System
510(k) Number	K210903	K161689	K120530
Classification Name	Abutment, Implant, Dental, Endosseous	Abutment, Implant, Dental, Endosseous	Abutment, Implant, Dental, Endosseous
Product Code	NHA	NHA	NHA
Regulation Number	872.3630	872.3630	872.3630
Intended Use	IS Multi Unit Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as bridges.	The OSSTEM Implant System – Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdenture	DENTIN® Dental Implants 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. DENTIN® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: CLASSIC, RAPID, PRESTIGE. One Stage Implants: ONE PIECE DENTIN® ONEPIECE Implants 3.0 mmd are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors.

			Indicated also for denture stabilization using multiple implants.
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design			
Abutment/Implant Interface Connection Type	Internal Non-Hex	Internal Non-Hex	Internal Non-Hex
Diameters (Ø)	4.8	4.8	5.0
Cuff(mm)	1.0/2.0/3.0/4.0/5.0/6.0	1.0/2.0/3.0/4.0/5.0	6.0
Post Height (mm)	2.2	-	-
Surface Treatment	N/A	TiN-Coating	TiN-Coating
Sterilization	End-User Moist Heat Sterilization	-	-
Principle of Operation	It is indicated for cement retained bridge restorations.	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.
Shelf Life	N/A	N/A	N/A
Similarities	The subject and primary predicate have same functions, materials, principle of operation and similar indications for use, design and dimensions.		
Differences	There are differences in Indications for Use, design, cuff length and surface treatment between the subject device and primary predicate. - Indications for Use: The subject device doesn't include the "O-ring" as the component; therefore, it is not intended to use for overdenture. Also, since the subject devices are only indicated for multi-unit restorations, it is not intended to use for crowns. As the indications for use of the subject device are in range of the predicate's, it doesn't affect the substantial equivalence. - Design, Cuff length, and Surface treatment: To support Ø4.8X6.0mm of subject abutment and surface treatment, K120530 was added as the reference device. These differences don't affect product's fundamental functions and substantial equivalence.		

2) IS Multi Unit Angled Abutment

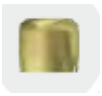
	Subject Device	Reference Device
Company	Neobiotech Co., Ltd	Dio Coporation
Device Name	IS Multi Unit Angled Abutment	UV Active Implant System- Angled Multi-Unit Abutment
510(k) Number	K210903	K182194
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136

Design			
Abutment/Implant Interface Connection Type	Internal Hex	Internal Non-Hex	Internal Hex
Diameters (Ø)	4.8		4.8
Cuff(mm)	1.0/2.0/3.0/4.0		1.5/2.5/3.5/4.5/5.5
Post Height(mm)	2.2		-
Angle(˚)	17/30		20/30
Surface Treatment	N/A		N/A
Sterilization	End-User Moist Heat Sterilization		-
Principle of Operation	It is indicated for cement retained bridge restorations.		It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.
Shelf Life	N/A		N/A
Similarities	The subject and reference devices have same intended use, functions, materials, surface treatment, general shape (design) and dimensions.		
Differences	There are slightly different designs and dimensions between subject and reference devices. These differences don't affect product's fundamental functions and substantial equivalence.		

3) Multi Unit Abutment Cylinder

	Subject Device	Reference Device
Company	Neobiotech Co., Ltd	MIS Implants Technologies Ltd.
Device Name	Multi Unit Abutment Cylinder	Cementing cap for Multi-Unit
510(k) Number	K210903	K180282
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters (Ø)	4.8	4.8
Lengths(mm)	5.0	3.3
Post Height(mm)	5.0	3.3
Surface Treatment	N/A	TiN-Coating
Sterilization	End-User Moist Heat Sterilization	Gamma irradiation
Principle of Operation	It is used to support the prosthesis, and it is connected with Multi Unit Abutment with Cylinder Screw.	It is used to support the prosthesis, and it is connected with Multi Unit Abutment with Cylinder Screw.
Shelf Life	N/A	5 years
Similarities	The subject and reference devices have same intended use, functions, materials, surface treatment, general shape (design) and dimensions.	
Differences	There are slightly different design and length. These differences don't affect product's fundamental functions and substantial equivalence.	

4) Multi Unit Healing Cap

	Subject Device	Reference Device
Company	Neobiotech Co., Ltd	MIS Implants Technologies Ltd.
Device Name	Multi Unit Healing Cap	Healing Cap
510(k) Number	K210903	K180282
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters(Ø)	4.8	4.8
Length (mm)	4.1	4.3
Post Height (mm)	4.1	4.3
Surface Treatment	N/A	TiN-Coating
Sterilization	Gamma irradiation	-
Principle of Operation	It is connected to the dental Abutment during soft tissue healing period combined with Implant. It should be removed when the superstructure is set up.	It is connected to the dental Abutment during soft tissue healing period combined with Implant. It should be removed when the superstructure is set up.
Shelf Life	5 years	5 years
Similarities	The subject and reference devices have same intended use, functions, materials, general shape (design) and dimensions.	
Differences	There are slightly different design and length. These differences don't affect product's fundamental functions and substantial equivalence.	

5) Multi Unit Temporary Cylinder

	Subject Device	Reference Device
Company	Neobiotech Co., Ltd	DIO Corporation
Device Name	Multi Unit Temporary Cylinder	Temporary Cylinder
510(k) Number	K210903	K182194
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters (Ø)	4.8/6.0	5.4
Length (mm)	11.0	12.0
Post Height (mm)	11.0	12.0
Surface Treatment	N/A	N/A
Sterilization	End-User Moist Heat Sterilization	-
Principle of Operation	It is designed to serve as a temporary dental prosthesis during the healing process until a permanent bridges are made.	It is designed to serve as a temporary dental prosthesis during the healing process until a permanent crown is made.
Shelf Life	N/A	N/A

Similarities	The subject and reference devices have same intended use, functions, materials, and general shape (design).
Differences	There are slightly different design and dimensions. These differences don't affect device's fundamental functions and substantial equivalence.

6) IS Multi Unit Angled Abutment Screw

	Subject Device	Reference Device
Company	Neobiotech Co., Ltd	Dio Coporation
Device Name	IS Multi Unit Angled Abutment Screw	Multi Angled Abutment Screw
510(k) Number	K210903	K182194
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters(Ø)	2.3	2.2
Length (mm)	8.3	6.0
Surface Treatment	N/A	N/A
Sterilization	End-User Moist Heat Sterilization	-
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.
Shelf Life	N/A	N/A
Similarities	The subject and reference devices have same intended use, functions, materials, and general shape (design).	
Differences	There are slightly different design and dimensions. These differences don't affect device's fundamental functions and substantial equivalence.	

7) Cylinder Screw

	Subject Device	Reference Device
Company	Neobiotech Co., Ltd	Dio Coporation
Device Name	Cylinder Screw	Cylinder Screw
510(k) Number	K210903	K182194
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters(Ø)	2.3	2.15
Length (mm)	4.1	4.0
Surface Treatment	N/A	N/A
Sterilization	End-User Moist Heat Sterilization	-
Principle of Operation	This product is a screw for connected with Multi Unit Abutment (Straight/Angled) and Cylinder.	This product is a screw for connected with Multi Unit Abutment (Straight/Angled) and Cylinder.
Shelf Life	N/A	N/A
Similarities	The subject and reference devices have same intended use, functions, materials, and general shape (design).	
Differences	There are slightly different design and dimensions. These differences don't affect device's fundamental functions and substantial equivalence.	

Similarities:
IS Multi Unit Abutment System has same device characteristics with the Primary predicate devices, OSSTEM Implant System-Abutment (K161689) and commercially available products based on the indications for use, the technology used, the material composition employed and performance characteristics as predicate devices. The subject device has been supposed to performance and product validations prior to release. Testing including performance and fatigue test has been finished to ensure the devices comply with the applicable International standards and US FDA Guidance.

Differences:
There are differences in Indications for Use, design, cuff length and surface treatment between the subject device and primary predicate.

- Indications for Use: The subject device doesn't include the "O-ring" as the component; therefore, it is not intended to use for overdenture. As the indications for use of the subject device are in range of the predicate's, it doesn't affect the substantial equivalence.
- Design, Cuff length, and Surface treatment: To support Ø4.8X6.0mm of subject abutment and surface treatment, K182194 and K120530 were added as the reference device. These differences don't affect product's fundamental functions and substantial equivalence.

Non-clinical testing data:
The subject device was tested to evaluate its substantial equivalence according to the following standards.

- End User Sterilization Validation Test Report on IS Multi Unit Abutment Angled Abutment (Hex type) according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1
- Fatigue Test Report according to ISO 14801:2016

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

- Sterilization Validation Test on Healing Abutments according to ISO 11137-1,2,3 referenced in K181138
- Shelf-Life Test on Healing Abutments according to ASTM F1980 referenced in K181138
- Biocompatibility Test according to ISO 10993-1 referenced in K181138
- Bacterial Endotoxin Testing on Healing Abutments according to ANSI/AAMI ST72:2011, USP <161>, and USP <85>, referenced in K181138

The results of the above tests have met the criteria of the standards, and demonstrated the substantial equivalence with the predicate device.
The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion
IS Multi Unit Abutment System constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, IS Multi Unit Abutment System and its predicates are substantially equivalent.