August 14, 2019

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

Re: K190849
Trade/Device Name: IS-III active System_S-narrow Type
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 7, 2019
Received: July 15, 2019

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,

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190849

Device Name
IS-III active System_S-narrow Type

Indications for Use *(Describe)*
The IS-III active System_S-narrow Type is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.
The IS-III active System_S-narrow Type is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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: IS-III active System_S-narrow Type
- Common Name: Endosseous dental implant
- Classification Name: Endosseous dental implant
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: 08/13/2019

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

Primary Predicate

- K130462, Paltop Narrow Implant manufactured by Paltop Advanced Dental Solutions Ltd.

Reference Devices

- K150537, MiNi Internal Implant System by Megagen Implant Co., Ltd.
- K161244, s-Clean OneQ-SL Narrow Implant System by Dentis Co., Ltd.
- K171728, MOR 3.0mm and PUR NP 3.2mm Implant Systems, MOR 2.1 x 18mm and 2.4x18mm by Sterngold Dental, LLC.
- K181138, IS-III active System by Neobiotech Co., Ltd.
- K181178, S-mini active Fixture by Neobiotech Co., Ltd.

Indications for Use:
The IS-III active System_S-narrow Type is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.
The IS-III active System_S-narrow Type is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Device Description

IS-III active System_S-Narrow System is composed of IS-III active S-Narrow Type fixtures and Abutments. IS-III active Fixture_ S-Narrow Type is a thread type implant made of Titanium ELI according to ASTM F136 which will be placed in the alveolar bone to replace the function of the missing tooth. This device has connection between the upper prosthesis and the internal hex.

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.
The Fixture's diameters are 3.2 mm and the lengths are 8.5/10.0/11.5/ 13.0/ 15.0 mm. Tolerance of dimension shall be within ± 1% range.

IS-III active System_S-Narrow Type Abutments are composed as below:
IS Cover Screw, IS Healing Abutment, IS Cemented Abutment, IS Temporary Abutment and IS Abutment Screw

The dimensions of abutments are as following:

Name	Diameter (mm)	Platform diameter (mm)	Length (mm)	Gingiva Height (mm)	Angulation
IS Cover Screw_S-Narrow Type	Ø 3.0	-	4.8/5.8/6.4	0.4/1.4/2.0	0°
IS Healing Abutment_S-Narrow Type	Ø 3.0	2.61	7.4/9.4/11.4	3.0/5.0/7.0	0°
	Ø 3.8		7.4/9.4/11.4		0°
	Ø 4.3		7.4/8.4/9.4/ 11.4/13.4	3.0/4.0/5.0/ 7.0/9.0	0°
IS Cemented Abutment_S-Narrow Type	Ø 3.5	2.61	7.0	2.0	0°
	Ø 4.0		5.5/7.0		0°
IS Temporary Abutment_S-Narrow Type	Ø 3.0	2.61	14.1/13.5	1.5	0°
IS Abutment Screw_S-Narrow Type	Ø 2.0	-	10.2	-	0°

The features of each abutment are as following:

Name	Uses	Surface Treatment	Connection
IS Cover Screw _S-Narrow Type	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	N/A	Screw Retained
IS Healing Abutment _S-Narrow Type	Used to formation appropriate gingival shape during the soft tissue healing period combined with implant	N/A	Screw Retained
IS Cemented Abutment _S-Narrow Type	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	TiN-Coating	Hex, Non-Hex,
IS Temporary Abutment _S-Narrow Type		N/A	Hex, Non-Hex
IS Abutment Screw _S-Narrow Type	It is used to fix Abutment at the top of fixture	N/A	Screw Retained

Tolerance of dimension for Abutments shall be within ± 1% range.

The surface of IS Cemented Abutment_S-narrow Type was treated with TiN-Coated.
IS-III active Fixture_S-Narrow type, IS cover screw, and healing Abutments are provided sterilized. And other Abutments are provided non- sterilized.
IS-III active Fixture_S-Narrow Type is enclosed with Cover Screw in a packing. Other Abutments are enclosed with Abutment Screw in a packing.
All of above products including enclosed product are packed separately for convenience.

Materials:
The Fixtures and Abutments are made of Titanium ELI of ASTM F136.

Summaries of Technological Characteristics:

1) IS-III active Fixture_S-Narrow

	Subject Device	Primary Predicate	Reference Device	Reference Device
Company	Neobiotech Co., Ltd	Paltop Advanced Dental Solutions Ltd.	Neobiotech Co., Ltd.	Sterngold Dental, LLC
Device Name	IS-III active System_ S-Narrow Type	Paltop Narrow Implant	S-mini active Fixture	MOR 3.0mm and PUR NP 3.2mm Implant Systems, MOR 2.1 x 18mm and 2.4x18mm
510(k) Number	N/A	K130462	K181178	K171728
Device Classification Name	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Product Code	DZE, NHA	DZE, NHA	DZE	DZE, NHA
Regulation Number	872.3640	872.3640	872.3640	872.3640
Intended Use	The IS-III active System_S-narrow Type is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The IS-III active System_S-narrow Type is	The Paltop Narrow Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Narrow Implant is	The S-mini active Fixture is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing phase of permanent endosseous dental implant, such as artificial teeth, in order to restore chewing function in partially edentulous patients.	The MOR™ implants are intended to be used for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible to support single unit, and multiple unit restorations. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. These implants are intended for delayed loading. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. The MOR™ implants are only intended for use with straight abutments. The implant body is intended to be placed such no angle correction is necessary. The PUR Implants are intended to be used for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible to support single unit, and multiple unit restorations. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. These implants are intended

	indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.		for delayed loading. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. The PUR implants are only intended for use with straight abutments. The implant body is intended to be placed such no angle correction is necessary.
Material	Titanium ELI of ASTM F136	Titanium ELI of ASTM F136	Titanium ELI of ASTM F136	Titanium ELI of ASTM F136
Design				 (PUR Implant)
Anti-Rotational Feature	Internal Hex	Internal Hex	-	Internal Hex
Diameters(Ø)	3.2	3.25	2.5/3.0/3.5	3.2
Lengths(mm)	8.5/l0.0/l1.5/13.0/15.0	10.0/11.5/13.0/16.0	7.0/8.5/l0.0/11.5/13.0/15.0	8/10/12/14
Surface Treatment	SLA	SLA	SLA	Roughened-blasted and acid etched
Sterilization	Gamma 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.	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.
Shelf Life	5 Years	-	5 Years	-
Similarities	The IS-III active Fixture_S-Narrow Type has same device characteristics with the Primary predicate devices, Paltop Narrow Implant (K130462) such as diameters, Length, intended use, material, functions, general shape (Design), structure and applied production method are similar.			
Differences	8.5mm length of the device are smaller than the primary predicates. To support this discrepancy, K171728 was added as a reference device that includes an implant-abutment combination (Ø3.2mm X 8.0mm) that meets or exceeds the one (Ø3.2mm X 8.5mm) proposed in this submission.			

2) IS Cover Screw_S-Narrow

	Subject Device	Primary Predicate
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd
Device Name	IS-III active System_ S-Narrow Type	IS-III active System
510(k) Number	N/A	K181138
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters(Ø)	3.0	3.45
Lengths(mm)	4.8/5.8/6.4	5.85/6.85/7.45
Surface Treatment	N/A,	N/A
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.
Shelf Life	5 Years	5 Years
Similarities	The subject device has same designs, intended use, material, functions, principle of operation, shelf life and similar design and dimensions.	
Differences	There are slightly different dimensions.	

3) IS Healing Abutment_S-Narrow

	Subject Device	Primary Predicate Device
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd
Device Name	IS-III active System_ S-Narrow Type	IS-III active System
510(k) Number	N/A	K181138
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design		
Diameters(Ø)	3.0/3.8/4.3	4.0/4.5/4.8/5.5/6.0/6.8/8.0/9.0
Cuff(mm)	3.0/5.0/7.0	2.3/2.8/3.3/3.8/4.3/4.8/5.3/5.8/6.3/6.8/7.8/
Surface Treatment	N/A	N/A
Sterilization	Gamma Sterilization	Gamma Sterilization

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.
Shelf Life	5 Years	5 Years
Similarities	The subject device has same intended use, functions, material, surface treatment, principle of operation, shelf life and similar design and dimensions.	
Differences	There are slightly different designs and dimensions.	

4) IS Cemented Abutment_S-Narrow

	Subject Device		Primary Predicate Device		Reference Predicate Device
Company	Neobiotech Co., Ltd		Neobiotech Co., Ltd		MegaGen Implant Co., Ltd.
Device Name	IS-III active System_ S-Narrow Type		IS-III active System		MiNi Internal Implant System
510(k) Number	N/A		K181138		K150537
Material	Ti-6Al-4V ELI of ASTM F136		Ti-6Al-4V ELI of ASTM F136		Ti-6Al-4V ELI of ASTM F136
Design					
	Hex	Non-Hex	Hex	Non-Hex	
Diameters(Ø)	3.5/4.0		4.5/5.2/5.7/6.5		3.5
Lengths(mm)	5.5/7.0		4.0/4.5/5.5/7.0/8.0		5.0/7.0
Surface Treatment	TiN-Coating		TiN-Coating		TiN-Coating
Sterilization	N/A		N/A		N/A
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.		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 indications for use, functions, materials, surface treatment, general shape (design) and dimensions.				
Differences	There are slightly different designs and dimensions.				

5) IS Temporary Abutment_S-Narrow

	Subject Device		Reference Predicate Device	Reference Device	
Company	Neobiotech Co., Ltd		MegaGen Implant Co., Ltd.	Neobiotech Co., Ltd	
Device Name	IS-III active System_ S-Narrow Type		MiNi Internal Implant System	IS-III active System	
510(k) Number	N/A		K150537	K181138	
Material	Ti-6Al-4V ELI of ASTM F136		Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	
Design					
	Hex	Non-Hex		Hex	Non-Hex
Diameters(Ø)	3.0		3.0	4.5	
Length(mm)	14.1/13.5		12.0	11.1/13.1	
Surface Treatment	N/A		N/A	N/A	
Sterilization	N/A		N/A	N/A	
Principle of Operation	It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a permanent crown is made.		It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a permanent crown is made.	It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a permanent crown is made.	
Shelf Life	N/A		N/A	N/A	
Similarities	The subject and primary predicate have same indications for use, functions, materials, surface treatment, general shape (design) and diameters.				
Differences	Lengths of the device are longer than the primary predicates.				

6) IS Abutment Screw_S-Narrow

	Subject Device	Primary Predicate	Reference Device
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd	Dentis Co., Ltd
Device Name	IS-III active System_ S-Narrow Type	IS-III active System	s-Clean OneQ-SL Narrow Implant System
510(k) Number	N/A	K181138	K161244
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
Design			
Diameters(Ø)	2.0	2.3	2.03
Length (mm)	10.2	8.8	9.0

Surface Treatment	N/A	N/A	N/A
Sterilization	N/A	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.	This product is a screw for connected with Abutment and fixture.
Shelf Life	N/A	N/A	
Similarities	The subject and primary predicate have same indications for use, functions, materials, surface treatment, general shape (design) and diameters.		
Differences	Length of the device are longer than the primary predicates.		

Similarities:

The IS-III active Fixture_S-Narrow Type has same device characteristics with the Primary predicate devices, Paltop Narrow Implant (K130462) such as diameters, Length, intended use, general shape (Design), structure, fundamental technologies and applied production method are similar.
The IS-III active Abutments_S-Narrow Type are similar to other commercially available products based on the intended use, the technology used, the claims, 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 and US FDA Guidance.

Differences:

The differences between the subject device and the primary predicate device are length. 8.5mm length of the device are smaller than the primary predicates. To support this discrepancy, K171728 was added as a reference device that includes an implant-abutment combination (Ø3.2mm X 8.0mm) that meets or exceeds the one (Ø3.2mm X 8.5mm) proposed in this submission.

Non-clinical testing data:

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Sterilization Validation Test on Fixtures according to ISO 11137-1,2,3
- Shelf Life Test on Fixtures according to ASTM F1980
- Bacterial Endotoxin Test Report on Fixtures according to ANSI/AAMI ST72:2011, USP <161>, and USP <85>

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
- End User Sterilization Validation Test Report according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1 referenced in K181138
- Biocompatibility testing 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 on fixtures referenced in K181178
- Biocompatibility testing according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-6:2007, and ISO 10993-10:2010 on TiN Coated abutments 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-III active System_S-Narrow Type 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-III active System_S-Narrow Type and its predicates are substantially equivalent.