November 16, 2018

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

Re: K181137
Trade/Device Name: IT-III active System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 11, 2018
Received: October 17, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181137

Device Name
IT-III active System

Indications for Use *(Describe)*
The IT-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. IT-III active system is dedicated for two stage surgical procedures and 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: IT-III active 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: 11/16/2018

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

Primary Predicate

- K090527, Sinus Quick ™ IT System manufactured by Neobiotech Co., Ltd.

Reference Devices

- K052957, Implantium Prosthetics manufactured by Dentium Co., Ltd.
- K070228, Implantium Prosthetics manufactured by Dentium Co., Ltd.
- K112045, Simple Line II Abutment system manufactured by Dentium Co., Ltd.
- K120503, CMI Implant IS II active manufactured by Neobiotech Co., Ltd.
- K121585, TS Implant System manufactured by Osstem Implant Co., Ltd.
- K160828, Implantium® / SuperLine® Prosthetics manufactured by Dentium Co., Ltd.
- K181138, IS-III active System manufactured by Neobiotech Co., Ltd.

Indication for Use:
The IT-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. IT-III active system is dedicated for two stage surgical procedures and for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Device Description

IT-III active System is composed of Fixture and Abutments. IT-III active Fixture is a thread type implant made of Pure titanium according to ASTM F67 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 Octa.,

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 dimensions are as following:

Name	Diameter (mm)	G.Collar	Length (mm)
IT-III active Fixture	Ø 3.5	1.8	8.5/10.0/11.5/13.0/15.0
		2.8	
	Ø 4.0/4.5/5.0/5.5	1.8	7.0/8.5/10.0/11.5/13.0/15.0
		2.8	
	Ø 6.0/7.0	1.8	7.0/8.5/10.0/11.5/13.0
		2.8	

Tolerance of dimension shall be within ± 1% range.

The IT –III active System Abutment are composed as below;
IT Cover screw, IT Healing Abutment, IT Solid Abutment, IT Excellent Solid Abutment, Protective Cap, IT Cemented Abutment, IT Pre Angled Abutment, IT Collared Angled Abutment, IT Gold UCLA Abutment,
IT Cemented Abutment Screw and IT Angled Abutment Screw
The dimensions of abutments are as following:

Name	Diameter (mm)	Length of Cuff (mm)
IS Cover Screw	Ø 5.5/6.9	6.0
IT Healing Abutment	Ø 5.8	Cuff: 2.5/3.5/4.5/5.5/6.5
	Ø 6.3/7.1	Cuff: 1.5/2.5/3.5/4.5/5.5/6.5
	Ø 7.2	Cuff: 1.5/2.5/3.5
IT Solid Abutment	Ø 3.5/4.3	4.0/5.5/7.0
IT Excellent Solid Abutment	Ø 4.35	5.25/6.75
Protective cap	Ø 5.45	5.45/6.0/6.95/7.5/8.45/9.0
	Ø 7.2	6.0/7.5/9.0
IT Cemented Abutment	Ø 4.3	6.0
	Ø 4.85	5.8
	Ø 5.5	6.0
	Ø 6.55	5.8
IT Pre Angled Abutment	Ø 3.7	9.5
	Ø 4.3	9.68
IT Collared Angled Abutment	Ø 5.5	7.0
IT Gold UCLA Abutment	Ø 5.5	10.0
IT Cemented Abutment Screw	Ø 2.55	7.55
IT Angled Abutment Screw	Ø 2.55	6.75

The Abutments have below features:

Name	Uses	Surface	Connection
IT 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	N/A	Screw retained
IT Healing Abutment	Used to formation appropriate gingival shape during the soft tissue healing period combined with implant	N/A	
IT Solid Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	Anodizing (Blue/yellow) Non-Anodizing,	
IT Excellent Solid Abutment			
IT Cemented Abutment		TiN-Coating	Internal Octa, Non-Octa, SCRP
IT Pre Angled Abutment		N/A	Internal, Octa, Non-Octa
IT Collared Angled Abutment		TiN-Coating	
IT Gold UCLA Abutment		N/A	
Protective Cap	Used to protect Solid Abutments in the oral cavity.	N/A	-
IT Cemented Abutment screw	It is used to fix Abutment at the top of fixture.	N/A	Screw retained
IT Angled Abutment Screw		N/A	

Tolerance of dimension for Abutments shall be within ± 1% range.
The surface of IT Cemented Abutment and IT Collared Angled Abutment was treated with TiN-Coated.
IT-III active Fixture, IT Cover Screw and IT Healing Abutment are provided sterilized.
And the other Abutments are provided non-sterilized.
IT-III active Fixture is enclosed with cover screw in a packing. Other Abutments are enclosed with abutment screw in a packing. The Solid Abutment and Excellent Solid Abutment are enclosed with Protective cap.

Enclosed package as a set is following:

Product Name	Enclosed product
IT-III active Fixture	IT Cover Screw
IT Solid Abutment	Protective Cap
IT Excellent Solid Abutment	Protective Cap
IT Cemented Abutment	IT Cemented Abutment Screw
IT Pre Angled Abutment	IT Angled Abutment Screw
IT Collared Angled Abutment	IT Cemented Abutment Screw
IT Gold UCLA Abutment	IT Cemented Abutment Screw
IT Healing Abutment	N/A

All of above products including enclosed product are packed separately for convenience.

Materials:

- The fixture is fabricated from Pure titanium of ASTM F67
- The Abutments (IT Cover Screw, IT Healing Abutment, IT Solid Abutment, IT Excellent Solid Abutment, IT Pre Angled Abutment, IT Collared Angled Abutment, IT Cemented Abutment Screw, IT Angled Abutment Screw) are fabricated from Ti-6Al-4V ELI of ASTM F136.
- The IT Gold UCLA Abutment is fabricated from Gold Alloy and Polyoxymethylene(POM) of ASTM F1855.
- The Protective Cap is fabricated from Polyoxymethylene(POM) of ASTM F1855.

Summaries of Technology Characteristics:

1) IT-III active Fixture

	Subject Device	Primary Predicate	Reference Devices
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd.	Neobiotech Co., Ltd.
Device Name	IT-III active System	Sinus Quick ™ IT System	CMI Implant IS II active
510(k) Number	K181137	K090527	K120503
Device Classification Name	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Product Code	DZE	DZE	DZE
Regulation	872.3640	872.3640	872.3640
Indications for Use	The IT-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. IT-III active system is dedicated for two stage surgical procedures and for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Sinus Quick™ IT 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. IT System is dedicated for two stage surgical procedures and for immediate loading	The CMI Implant IS II active is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Material	Pure Titanium of ASTM F67	Pure Titanium of ASTM F67	Pure Titanium of ASTM F67
Design			
Anti-Rotational Feature	Internal Octa	Internal Octa	Internal Hex

Diameters(Ø)	3.5/4.0/4.5/5.0/5.5/6.0/7.0	3.5/4.0/5.0	3.5/4.0/4.5/5.0/5.5/6.0/7.0/8.0
Lengths(mm)	7.0/8.5/l0.0/11.5/13.0/15.0	8.5/10.0/11.5/13.0/15.0	7.3/8.5/10.0/11.5/13.0/15.0
Surface Treatment	SLA	RBM	SLA
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.
Shelf Life	5 Years	5 Years	5 Years
Similarities	The IT-III active Fixture has same device characteristics with the Primary predicate devices, Sinus Quick ™ IT System (K090527) such as diameters, Length, intended use, material, function, general shape (Design), structure and applied production method are similar.		
Differences	The differences between the subject device and the primary predicate device are surface treatment and upper part design. The surface treatment method of the subject fixture is SLA (Sandblasted with Large-grit and Acid-etching) and the surface treatment method of the primary Predicate device is RBM (Resorbable Blasting Media). To support this discrepancy, K120503 was added as reference predicate which was treated with SLA method. There is no micro groove in the neck of subject device, but primary predicate has it, and there is a 0.1 mm difference in screw pitch between 0.9 and 0.8. These differences do not raise any question of substantial equivalence to the declared predicates.		

2) IT Cover Screw

	Subject Device	Primary Predicate	Primary Predicate
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd.	Osstem Implant Co., Ltd.
Device Name	IT-III active System	Sinus Quick ™ IT System	TS Implant System
510(k) Number	K181137	K090527	K121585
Indications for Use	The IT-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. IT-III active system is dedicated for two stage surgical procedures and for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Sinus Quick™ IT 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. IT System is dedicated for two stage surgical procedures and for immediate loading	The TS 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture.

			TS Implant System is compatible with abutment in the ET/SS Implant System
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)	5.5/6.9	3.5/5.5/6.0	4.0/4.5/5.0/6.0/7.0
Lengths(mm)	6.0	6.0	-
Surface Treatment	N/A	N/A	Anodizing
Sterilization	Gamma Sterilization	Gamma Sterilization	-
Principle of Operation	Cover screw as a set of medical devices 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.	Cover screw as a set of medical devices 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.	Cover screw as a set of medical devices 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 and predicate devices have same intended use, material, functions principle of operation, shelf life and similar design and length as the primary predicate.		
Differences	There are slightly different diameters between the subject and primary predicate device. K121585 was added to support the large diameters of the subject Cover Screw such as 6.9mm		

3) IT Healing Abutment

	Subject Device	Primary Predicate	Reference Devices	Reference Device
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd.	Neobiotech Co., Ltd.	Dentium Co., Ltd.
Device Name	IT-III active System	Sinus Quick ™ IT System	CMI Implant IS System	Implantium Prosthetics
510(k)	K181137	K090527	K120503	K070228
Indications for Use	The IT-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	The Sinus Quick™ IT 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	The CMI Implant IS 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 System is dedicated for two stage surgical procedures and for immediate loading	Implantium Prosthetic is intended for use as an aid in prosthetic rehabilitation

	fixed bridgework. IT-III active system is dedicated for two stage surgical procedures and for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	retained, oroverdenture restorations, and terminal or intermediate Abutment support for fixed bridgework. IT System is dedicated for two stage surgical procedures and for immediate loading	when there is good primary stability and an appropriate occlusal load.	
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Titanium Grade 4 of ASTM F67
Design				
Diameters(Ø)	5.8/6.3/7.1/7.2	5.5	4.8/5.5/6.0/6.8	4.0/4.5/5.5/6.5/7.5/8.5/9.5
Cuff(mm)	1.5/2.5/3.5/4.5/5.5/6.5	2.0/3.0/4.0	2.0/3.0/4.0/5.0/6.0/7.0/8.0	2.0/3.5/5.0/7.0
Surface Treatment	N/A	N/A	N/A	N/A
Sterilization	Gamma Sterilization	Gamma 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.	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.	Implantium Prosthetic is intended for use as an aid in prosthetic rehabilitation.
Shelf Life	5 Years	5 Years	5 Years	-
Similarities	The subject and predicate devices have same intended use, material, function, principle of operation, shelf life and general shape (design) and Cuff as the primary predicate.			
Differences	There are slightly different diameters and cuffs between the subject and primary predicate device. K120503 was added to support the long lengths of the subject healing abutments such as 4.5,5.5and 6.5mm K070228 was added to support the large diameters of the subject healing abutments such as 7.1 and 7.2mm			

4) IT Solid Abutment/IT Excellent Solid Abutment

	Subject Device	Primary Predicate	Reference Devices
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd.	Dentium Co., Ltd.
Device Name	IT-III active System	Sinus Quick ™ IT System	SimpleLineII Abutment System
510(k)	K181137	K090527	K112045
Indications for Use	The IT-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. IT-III active system is dedicated for two stage surgical procedures and for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Sinus Quick™ IT 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. IT System is dedicated for two stage surgical procedures and for immediate loading	The SimpleLine II Abutment is intended for use as an aid in prosthetic rehabilitation.
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
IT Solid Abutment			
Design			
Diameters(Ø)	3.5/4.3	3.5/4.3	4.8/6.5
Lengths(mm)	4.0/5.5/7.0	4.0/5.5/7.0	
Surface Treatment	Andodizing/ Non-Anodizing	Andodizing/ Non-Anodizing	N/A
IT Excellent Solid Abutment			
Design			-
Diameters(Ø)	4.35	5.2/5.7	-
Lengths(mm)	5.25/6.75	4.5/5.5/7.0	-
Surface Treatment	Andodizing/ Non-Anodizing	Andodizing	Non-coating
Sterilization	N/A components are end-user sterilized	N/A components are end-user sterilized	N/A components are end-user sterilized
Principle of Operation	This product is a superstructure which is connects with the fixture. It is a one-body type Abutment of	This product is a superstructure which is connects with the fixture. It is a one-body type Abutment of screw-retained that does not	This product is a superstructure which is connects with the fixture. It is a one-body type Abutment of screw-retained that does not

	screw-retained that does not require an Abutment screw. It replaces the functions of the missing teeth as a dental Abutment	require an Abutment screw. It replaces the functions of the missing teeth as a dental Abutment	require an Abutment screw. It replaces the functions of the missing teeth as a dental Abutment.
Shelf Life	N/A	N/A	N/A
Similarities	The subject and predicate devices have same intended use, material, function, surface treatment (Anodizing), principle of operation, shelf life and similar design and dimensions.		
Differences	The dimensions are slightly different but it doesn't affect device's fundamental functions.		

5) Protective Cap

	Subject Device	Primary Predicate	Reference Devices
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd.	Neobiotech Co., Ltd.
Device Name	IT-III active System	Sinus Quick ™ IT System	CMI Implant IS System
510(k) Number	K181137	K090527	K120503
Indications for Use	The IT-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. IT-III active system is dedicated for two stage surgical procedures and for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Sinus Quick™ IT 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, oroverdenture restorations, and terminal or intermediate Abutment support for fixed bridgework. IT System is dedicated for two stage surgical procedures and for immediate loading	The CMI Implant IS 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 System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load.
Material	Polyoxymethylene(POM) of ASTM F1855	Polyoxymethylene(POM) of ASTM F1855	Polyoxymethylene(POM)of ASTM F1855
Design			
Diameters(Ø)	5.45/7.2	5.45/7.2	4.5,/5.2/5.7/6.5
Lengths(mm)	5.45/6.0/6.95/7.5/8.45/9.0	4.0/.5.5/7.0	7.4/8.4/9.4
Surface Treatment	N/A	N/A	N/A
Sterilization	N/A components are end-user sterilized	N/A components are end-user sterilized	N/A components are end-user sterilized
Principle of Operation	Used to protect Solid Abutments in the oral cavity.	Used to protect Solid Abutments in the oral cavity	Used to protect Solid Abutments in the oral cavity
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	The design of the devices is slightly different but it doesn't affect device's fundamental functions.		

6) IT Cemented Abutment/ IT Collared Angled Abutment /IT Pre Angled Abutment

	Subject Device			Primary Predicate		Reference Devices	Reference Devices
Company	Neobiotech Co., Ltd			Neobiotech Co., Ltd.		Dentium Co., Ltd.	OSSTEM Implant Co., Ltd..
Device Name	IT-III active System			Sinus Quick ™ IT System		Implantium Prosthetics	TS Implant System
510(k)	K181137			K090527		K052957	K121585
Indications for Use	The IT-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. IT-III active system is dedicated for two stage surgical procedures and for immediate loading when good primary stability is achieved and with appropriate occlusal loading.			The Sinus Quick™ IT 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. IT System is dedicated for two stage surgical procedures and for immediate loading		Implantium Prosthetics is intended for use as an aid in prosthetic rehabilitation	The TS 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The abutment is intended for use with a dental implant fixture to provide support for prosthetic restorations such as crowns, bridges, or overdenture. TS Implant System is compatible with abutment in the ET/SS Implant System.
Material	Ti-6Al-4V ELI of ASTM F136			Ti-6Al-4V ELI of ASTM F136		Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
IT Cemented Abutment							
Design							
	Octa	Non-Octa	SCRP	Octa	Non-Octa		Hex/Non-Hex
Diameters(Ø)	4.3/4.85/5.5/6.55			5.2/5.7		4.5/5.5/6.5	4.5/5.0/6.0/7.0
Lengths(mm)	5.8/6.0			4.5/5.5/6.0/7.0/8.0		9.2~13.7	4.0/5.5/7.0
Surface Treatment	TiN-Coating			TiN-Coating		TiN-Coating	TiN-Coating

IT Collared Angled Abutment						
Design						
	Octa	Non-Octa	Octa	Non-		Hex/Non-Hex
Diameters(Ø)	5.5		5.2/5.7		4.5/5.5	4.5/5.0/6.0
Lengths(mm)	7		7		13.3	8
Angle (°)	15/25		15/25		15/25	17
Surface Treatment	TiN-Coating		TiN-Coating		TiN-Coating	TiN-Coating
IT Pre Angled Abutment						
Design						-
	Octa	Non-Octa	Octa	Non-Octa		-
Diameters(Ø)	3.7/4.3		3.5		4.5~5.5	-
Lengths(mm)	9.5/9.68		9.5		15.31	-
Angle (°)	15/25		15/25		15/25	-
Surface Treatment	N/A		N/A		N/A	-
Sterilization	N/A components are end-user sterilized		N/A components are end-user sterilized		N/A components are end-user sterilized	-
Principle of Operation	This product is a superstructure which is connects with the fixture using the enclosed Abutment screw. It replaces the functions of the missing teeth as a dental Abutment.		This product is a superstructure which is connect with the fixture using the enclosed Abutment screw. It replaces the functions of the missing teeth as a dental Abutment.		This product is a superstructure which is connect with the fixture using the enclosed Abutment screw. It replaces the functions of the missing teeth as a dental Abutment.	This product is a superstructure which is connect with the fixture using the enclosed Abutment screw. It replaces the functions of the missing teeth as a dental Abutment.
Shelf Life	N/A		N/A		N/A	N/A
Similarities	The subject and predicate devices have same intended use, material, function, coating material (TiN), angulation, principle of operation, and general shape (design) and dimensions.					
Differences	The dimensions are slightly different but it doesn't affect device's fundamental functions. There are slightly different diameters and lengths between the subject and primary predicate device. K052957 was added to support the long lengths of the subject Cemented Abutment, Collared Angled Abutment, Pre Angled Abutment K121585 was added to support the large diameters of the subject Cemented Abutment such as 6.55mm					

7) IT Gold UCLA Abutment

	Subject Device	Primary Predicate	Reference Devices
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd.	Dentium Co., Ltd.
Device Name	IT-III active System	Sinus Quick ™ IT System	Implantium® / SuperLine® Prosthetics
510(k)	K181137	K090527	K160828
Indications for Use	The IT-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. IT-III active system is dedicated for two stage surgical procedures and for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Sinus Quick™ IT 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. IT System is dedicated for two stage surgical procedures and for immediate loading	Dentium Implantium®/ SuperLine® Prosthetics is intended for use as an aid in prosthetic rehabilitation
Material	Gold Alloy / Polyoxymethylene(POM) of ASTM F1855	Gold Alloy / Polyoxymethylene(POM) of ASTM F1855	Gold Alloy / Polyoxymethylene(POM) of ASTM F1855
Design,	  Octa / Non-Octa	  Octa / Non-Octa	
Diameters(Ø)	5.5	5.5	4.5
Lengths(mm)	10	13	19.2
Surface Treatment	N/A	N/A	N/A
Sterilization	N/A components are end-user sterilized	N/A components are end-user sterilized	N/A components are end-user sterilized
Principle of Operation	It is used when there are restrictions on the prosthesis production because of path, aesthetics, and space of fixture. Production the prosthesis by casting with dental alloy after wax up with desired shape	It is used when there are restrictions on the prosthesis production because of path, aesthetics, and space of fixture. Production the prosthesis by casting with dental alloy after wax up with desired shape	It is used when there are restrictions on the prosthesis production because of path, aesthetics, and space of fixture. Production the prosthesis by casting with dental alloy after wax up with desired shape.
Shelf Life	N/A	N/A	N/A
Similarities	The subject and predicate devices have same intended use, material, function, principle of operation, and general shape (design) and dimensions		
Differences	The dimensions are slightly different but it doesn't affect device's fundamental functions.		

8) IT Cemented Abutment Screw/ IT Angled Abutment Screw

	Subject Device	Primary Predicate
Company	Neobiotech Co., Ltd	Neobiotech Co., Ltd.
Device Name	IT-III active System	Sinus Quick ™ IT System
510(k)	K181137	K090527
Indications for Use	The IT-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. IT-III active system is dedicated for two stage surgical procedures and for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Sinus Quick™ IT 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, oroverdenture restorations, and terminal or intermediate Abutment support for fixed bridgework. IT System is dedicated for two stage surgical procedures and for immediate loading
Material	Ti-6Al-4V ELI of ASTM F136	Ti-6Al-4V ELI of ASTM F136
IT Cemented Abutment Screw		
Design		
Diameters(Ø)	2.55	2.55
Length(mm)	7.55	7.55
IT Angled Abutment Screw		
Design		-
Diameters(⌀)	2.55	-
Length(mm)	6.75	-
Surface Treatment	N/A	N/A
Sterilization	N/A components are end-user sterilized	N/A components are end-user sterilized
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 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 and substantial equivalence to the declared predicates.	

Similarities:

The IT-III active Fixture has same device characteristics with the Primary predicate devices, Sinus Quick™ IT System (K090527)such as diameters, Length, intended use, general shape (Design), structure, fundamental technologies and applied production method are similar.

The IT-III active Abutments 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 surface treatment. The surface treatment method of the subject fixture is SLA (Sandblasted with Large-grit and Acid-etching) and the surface treatment method of the primary Predicate device is RBM (Resorbable Blasting Media). To support this discrepancy, K120503 was selected as reference predicate for the fixtures.
Another difference between the subject and primary predicate device are the addition of diameters above 5.0 mm and lengths less than 8.5 mm. However, our reference predicate, K120503 includes the fixtures that meet or exceed diameters above 5.0 mm and lengths less than 8.5 mm in this submission, these differences do not raise any question of substantial equivalence to the declared predicates.

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

- Fatigue Testing according to ISO 14801:2016 under the worst-case scenario
- Sterilization Testing according to ISO 11137-1:2006, ISO 11137-2:2013, and ISO 11137-3:2006
- Shelf Life Testing according to ASTM F1980
- Bacterial Endotoxin Test Report according to ANSI/AAMI ST72:2011, USP <161>, and USP <85>
- Biocompatibility Evaluation according to ISO 10993-1:2009

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.
Biocompatibility Test conducted on our own predicate device, K181138 was leveraged for the subject device, and it demonstrates that the subject device is biocompatible.
Fatigue testing for IT-III active fixture and angled Abutment was conducted according to the “Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment” and ISO 14801:2016 Dentistry - Fatigue test for endosseous dental implants under the worst-case scenario to ensure that the subject device is strong enough for its intended use.
End user sterilization Validation performed on our own predicate device, K181138 was leveraged for the subject device.
The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion
IT-III active 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, IT-III active System and its predicates are substantially equivalent.