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

March 28, 2024

Re: K232049
Trade/Device Name: IS-III active Short Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: February 29, 2024
Received: February 29, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232049

Device Name
IS-III active Short Implant

Indications for Use *(Describe)*
IS-III active Short Implants are 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. The IS-III active Short Implants are indicated for the molar region with delayed 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

Submitter
Neobiotech. Co., Ltd.
Young-Ku, Heo
#10F, 36, Digital-ro 27 gil
Guro-gu, Seoul 08381
South Korea
Email: yujin.choi@neobiotech.com
Tel. +82-2-582-2885
Fax. +82-2-582-2883

Official Correspondent
Withus Group Inc
April Lee
106 Superior,
Irvine, CA 92620
USA
Email: withus6664@gmail.com
Phone: 1-909-274-9971
Fax: 1-909-460-8122

Device Information

- Trade Name: IS-III active Short Implant
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Primary Product Code: DZE
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: 03/28/2024

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

Primary Predicate

- K121585, TS Implant System manufactured by OSSTEM Implant Co., Ltd.

Reference Devices

- K181138, IS-III active System by Neobiotech Co., Ltd.
- K103089, MIS Short Implants by MIS implants Technologies Ltd.
- K221866, S-Plant Dental Implant System by IDIS Co., Ltd.

Indications for Use:
IS-III active Short Implants are 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. The IS-III active Short Implants are indicated for the molar region with delayed loading.

Device Description

IS-III active Short Implant is a thread type implant made of pure titanium according to ASTM F 67 and supplied sterile, 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 (mandibular or maxillary bone). The Fixture's diameters are 5.0/5.5/6.0mm and the length is 6.6 mm. Tolerance of dimension shall be within ± 1% range.

The dimensions are as following:

Name	Fixture Type	Diameter (mm)	Length (mm)	Material
IS-III active Short Implant		ø 5.0/5.5/6.0	6.6	TI CP4 (ASTM F67)

The subject devices are compatible with the following Prosthesis made by Neobiotech Co., Ltd.

510(K)	Abutment Name	Diameter(ø)	Length or Cuff(mm)
K181138	IS Cover Screw	3.6	6.4
	IS Healing Abutment	4.0/4.5 4.8/5.5/6.0/ 6.8/8.0/9.0	Cuff: 2.1/2.3/2.8/3.3/ 3.8/4.1/4.3/4.8/5.3/ 5.8/6.1/6.3/6.8/7.8/ 8.1/8.8/10.1
	IS Encoded Healing Abutment	4.0/4.6/5.3/5.8/6.6/8.0/9.0	Cuff: 2.3/3.3/4.3/5.3/6.3/7.3
	IS Encoded Healing Abutment Screw	Screw: 2.3	Screw: 8.4/9.4/10.4/11.4/12.4/13.4
	IS Solid Abutment	4.5/5.2/5.7/6.5	4.0/4.5/5.5/7.0
	IS Cemented Abutment	4.5/5.2/5.7/6.5	4.0/4.5/5.5/7.0/8.0
	IS Shapable Abutment	4.5/5.2/5.7/6.5	8.1/11.1
	IS Angled Abutment	4.5/5.2/5.7 Angle (°) : 15/25	7.0
	IS Ball Abutment	3.5	11.1/12.1/13.1/14.1/15.1/16.1
	IS Ball Abutment_Component	Housing:5.0 Retainer:5.0 O-Ring:4.6/4.7	Housing:4.0 Retainer:2.0 O-Ring: -
	IS Gold UCLA Abutment	4.5	10.0
	IS Temporary Abutment	4.5/5.2	6.0/8.0/11.5
	Protective Cap	5.0/5.7/6.2/7.1	5.5/6.3/7.3/ 8.8/7.75/9.25
	IS Abutment Screw	2.3	8.8/8.3

IS-III active Short Implant can be enclosed with IS Cover Screw cleared in K181138 in a packing or can be packed separately for convenience. IS-III active Short Implant is provided in sterilized by gamma rays, and valid for 5 years.

Summaries of Technological Characteristics:
IS-III active Short Implant is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

	Subject Device	Primary Device	Reference Device	Reference Device
Company	Neobiotech Co., Ltd	OSSTEM Implant Co., Ltd.	MIS implants Technologies	IDIS Co., Ltd.
Device Name	IS-III active Short Implant	TS Implant System	MIS Short Implants	S-Plant Dental Implant System
510(k) Number	N/A	K121585	K103089	K221866
Device Classification Name	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Product Code	DZE	DZE, NHA	DZE	DZE, NHA
Regulation Number	872.3640	872.3640	872.3640	372.3640
Indications for Use	IS-III active Short Implants are 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. The IS-III active Short Implants are indicated for the molar region with delayed 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.	MIS dental implants are 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, in order to restore a patient's chewing function. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. MIS short implants are to be used only with straight abutments.	The S-Plant Dental Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The smaller SPlant Dental Implants (Ø3.4, 3.6, 3.8, 4.2, 4.7, 5.2 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger S-Plant Dental Implants (Ø6.0, 7.0 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading. Dual abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft

				tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.
Material	Titanium Grade 4 of ASTM F67	Titanium Grade 4 of ASTM F67	Ti-6Al-4V ELI of ASTM F136	Titanium Grade 4 of ASTM F67
Design				-
Structure	- Internal Hex - Submerge Type - Tapered body shape - Cutting edge for self-tapping	- Internal Hex - Submerge Type - Tapered body shape - Cutting edge for self-tapping	Internal Hex	-
Dimension	Ø5.0/5.5/6.0 X 6.6mm	Ø5.1/5.95/6.8 X 6.2mm	Ø 4.2/5.0/6.0 X 6.0mm	Ø 6.0 x 7.0, 8.5, 10.0, 11.5 mm
Lengths(mm)	Total Length (mm): 6.6 Implantable Length (mm): 6.6 Threaded length (mm): 6.6	Total Length (mm): 6.2 Implantable Length (mm): 6.2 Threaded length (mm): 6.2	6.0	-
Surface Treatment	Sand blasting & Acid Etching	Sand blasting & Acid Etching	Sand blasting & Acid Etching	Sand blasting & Acid Etching
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	8 Years	8 Years	-
Compatible Abutments	Straight and angled abutments	Straight and angled abutments	Straight abutment only	-

Similarities	The IS-III active Short Implants have same device characteristics with the Primary devices, TS Implant System (K121585) such as the intended use, material, functions, general shape (Design), connection type, structure and applied production method are similar.
Differences	The differences between the subject device and the primary device, TS Implant System (K121585) are the indications for Use, diameter, and length. The subject device short implants are compatible with own previously cleared reference device abutments in K181138. The range of diameter of the subject devices is wider and smaller than the primary Device. To support the smaller diameter, Reference Device, MIS Short Implants(K103089) have additionally been provided. The total lengths of the subject short implant devices are longer than the identified primary predicate device, K121585. To support the differences in diameter, bench testing of bone to implant contact surface area analysis, comparative surface area analysis, and pull-out testing, were performed to demonstrate the substantial equivalence of implantable surface areas with the identified primary predicate device K121585. The proposed implant body dimensions for 6.0mm diameter are supported by the reference device K221866. Therefore, these differences do not impact substantial equivalence.

Non-clinical testing data:

Below tests were performed on subject device:

- Fatigue Testing according to ISO 14801:2016 under the worst-case scenario
- Surface area comparison analysis
- Axial Pull-Out testing according to ASTM F 543-17 A.3

Below tests were performed for predicate device, K181138 and leveraged for the subject device:

- 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
- Gamma sterilization validation Test Report according to ISO 11137-1, ISO 11137-2 and ISO 11137-3
- Shelf Life Test on Fixtures according to ASTM F 1980
- Bacterial Endotoxin Test Report on Fixtures according to ANSI/AAMI ST72:2011, USP <161>, and USP <85>

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.

Sterilization and Shelf Life Testing

For devices provided sterile, 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.

Biocompatibility Testing

The Biocompatibility Test was conducted on the reference device, K181138 and leveraged for the subject device because both products are manufactured with the same material and manufacturing process. It demonstrates that the subject device is biocompatible and substantial equivalence with the predicate.

Surface area Analysis

Surface area for full external area and for bone resorption of 3mm before surface treatment have been evaluated for subject device and the predicate device, TS Implant System by OSSTEM Implant Co., Ltd. (K121585) under the worst-case implant. And the subject device has the same material as the cleared previous device, which is consist of Pure Titanium. And the subject device and the predicate device are applied to same ASTM standard in accordance with ASTM F 67. Results showed that subject devices are substantially equivalent.

Comparative Bone to Implant Contact Surface Area Analysis

Contact surface area was analyzed in comparison to both subject device and predicate device, K121585, under worst case implant.

Fatigue Testing

Due to the length of the subject devices, Dynamic fatigue tests were newly performed to demonstrate the mechanical value as compared to the predicate devices, TS Implant System by OSSTEM Implant Co., Ltd. (K121585) according to the FDA guidance document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" and ISO 14801. The Results of fatigue testing showed that subject devices are substantially equivalent under the worst-case scenario.

Axial Pull-Out Testing

Due to the length of the subject devices, Pull-out tests were newly performed to demonstrate the mechanical value as compared to the predicate devices, TS Implant System by OSSTEM Implant Co., Ltd. (K121585) according to ASTM F543-17 A3 and each manufacturer drilling sequence. The Results of Pull-out Strength showed that subject devices are substantially equivalent under the worst-case scenario.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic IS-III active Short Implants in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices", Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.
The results of the above non-clinical tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

Conclusion

IS-III active Short Implant 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 Short Implants and their predicates are substantially equivalent.