December 19, 2023

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

Re: K233163
Trade/Device Name: ZENEX Implant System_Short
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: September 26, 2023
Received: September 27, 2023

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
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OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K233163

Device Name
ZENEX Implant System_Short

Indications for Use *(Describe)*
The ZENEX Implant System_Short 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. ZENEX Implant System_Short are intended to be used in the molar region.

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: ZENEX Implant System_Short
- 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: 12/19/2023

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 Predicates

- K211090, Zenex Implant System manufactured by Izenimplant Co., Ltd.

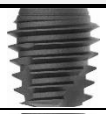
Indications for Use:
The ZENEX Implant System_Short is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including: cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. ZENEX Implant System_Short are intended to be used in the molar region.

Device Description

ZENEX Implant System_Short 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 in order to support or maintain the prosthetic tooth or denture when a patient's teeth are partially or totally lost.

The fixture's surface is treated with SLA (Sandblasted with Large-grit and Acid-etching). The entire length of 6.25mm of implant bodies are implanted into the bone to connect prosthetic devices of a dental implant set with the human body (mandibular or maxillary bone).

There are 2 types of fixtures, and the dimensions are as following:

Name	Fixture Type	Diameter (mm)	Length (mm)	Material
ZENEX Implant System_Short (I-System)		Ø 5.05/5.4/5.9/6.75	6.25mm	Ti CP4 (ASTM F67)
ZENEX Implant System_Short (T-System)		Ø 5.05/5.4/5.9/6.75	6.25mm	

Tolerance of dimension shall be within ± 1% range.

The subject devices are compatible with the following abutments made by Izenimplant Co., Ltd.

510(K)	Abutment Name	Diameter(Ø)	Angulation	Length or Cuff(mm)
K211090	Cover Screw	I-System: Ø3.6 T-System: Ø3.6/Ø3.9	0˚	P/H: 0.4/1.4/2.0
	Healing Abutment	I-System: Ø4.3/Ø4.8/Ø5.5/Ø6.0/Ø6.8/Ø8.0/Ø9.0 T-System: Ø4.8/Ø5.3/Ø6.3/Ø7.3/Ø8.3	0˚	P/H: 2/3/4/5/6/7/9
	Cemented Abutment	I-System: Ø4.5/Ø5.2/Ø5.7/Ø6.5 T-System: Ø4.5/Ø5.0/Ø6.0/Ø7.0	0˚	G/H: 1/2/3/4/5/6/7 PH: 4/5/5.5/7
	Angled Abutment	I-System: Ø4.5/Ø5.2/Ø5.7 T-System: Ø4.5/Ø5.0/Ø6.0	I-System: 15˚/25˚ T-System: 17˚	G/H: 2/3/4 P/H: 7
	Temporary Abutment	I-System: Ø4.5 T-System: Ø4.5	0˚	G/H: 1/3 PH: 10
	Ball Abutment	I-System: Ø3.5 T-System: Ø3.5	0˚	G/H: 1/2/3/4/5/6
	Abutment Screw	I-System: Ø2.3 T-System: Ø2.3	0˚	I-System: 8.2 T-System: 8.35

ZENEX Implant System_Shorts are provided sterile, and valid for 5 years.

Summaries of Technological Characteristics:

ZENEX Implant System_Short are 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 Predicate
Company	Izenimplant Co., Ltd.	OSSTEM Implant Co., Ltd.
Device Name	ZENEX Implant System_Short	TS Implant System
510(k) Number	N/A	K121585
Device Classification Name	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Product Code	DZE	DZE, NHA
Regulation Number	872.3640	872.3640
Intended Use	The ZENEX Implant System_Short 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. ZENEX Implant System_Short are intended to be used in the molar region.	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.
Material	Titanium Grade 4 of ASTM F67	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
Diameters(Ø)	5.05/5.4/5.9/6.75	5.1/5.95/6.8
Lengths(mm)	6.25	6.2
Surface Treatment	Sand blasting & Acid Etching	Sand blasting & Acid Etching
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.
Shelf Life	5 Years	8 Years
Compatible Abutments	Straight and angled abutments	Straight and angled abutments
Similarities	The ZENEX Implant System_Short have 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 difference of the indications for use between two devices is the subject device includes "ZENEX Implant System_Short are intended to be used in the molar region." and it is added because the predicate had the same explanation for the same diameter range. The subject device includes smaller diameter implant than the primary Device such as Ø5.05. To support the smaller diameter, bench testing was performed to demonstrate the substantial equivalence of implantable surface areas. And the whole length of the subject device is longer than the primary Device. But, for taking into consideration for the clinical risk of short implant, the subject device is intended to be placed into bone more deeply compared to primary device. Therefore, these differences don't affect the device's fundamental functions and 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

Below tests were performed for predicate device, K211090 and leveraged for the subject device:

- Biocompatibility testing according to ISO 10993-1:2009
- 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 leveraged from K211090.

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 predicate device, K211090 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, K121585 under the worst-case implant, following the surgical procedure according to the labeling for both systems. And the subject device has the same material as the predicate device, which consists of Pure Titanium. And the subject device and the

predicate device are applied to 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 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.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic ZENEX Implant System_Short 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

ZENEX Implant System_Short constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has similar intended use and fundamental scientific technology as its predicate devices. Therefore, ZENEX Implant System_Short and their predicates are substantially equivalent.