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

October 30, 3024

Re: K240560
Trade/Device Name: ZENEX Implant System_Long
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: February 28, 2024
Received: October 08, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*
K240560

Device Name
ZENEX Implant System_Long

Indications for Use *(Describe)*
ZENEX Implant System_Long 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 Implants in the 20 mm length when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

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_Long
- 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: 10/30/2024

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

Primary Predicate

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

Reference Devices

- K161604, Osstem Implant System manufactured by OSSTEM Implant Co., Ltd.
- K221453, S.I.N. Dental Implant System manufactured by S.I.N. – Sistema de Implante Nacional S.A.
- K222778, Osstem Implant System manufactured by OSSTEM Implant Co., Ltd.
- K232418, Single Platform SP1 Implant System manufactured by Southern Implants (Pty) Ltd.

Indications for Use:
ZENEX Implant System_Long 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 Implants in the 20 mm length when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

Device Description

ZENEX Implant System_Long 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).

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

Name	Fixture Type	Diameter (mm)	Length (mm)	Material
ZENEX Implant System_Long (ZENEX MULTI Fixture)		Ø 3.75/4.25	18mm/20mm	Ti CP4 (ASTM F67)
		Ø 4.6	18mm	
ZENEX Implant System_Long (ZENEX PLUS Fixture)		Ø 3.75/4.25	18mm/20mm	
		Ø 4.6	18mm	

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)	Multi-unit Loading
K211090	Cover Screw	I-System: Ø3.45 / Ø3.6 T-System: Ø3.0/Ø3.4/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: Ø4.3/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: Ø4.0/Ø4.5/Ø5.0/Ø6.0/Ø7.0	0˚	G/H: 1/2/3/4/5/6/7 PH: 4/5/5.5/7	Bridges
	Angled Abutment	I-System: Ø4.5/Ø5.2/Ø5.7 T-System: Ø4.0/Ø4.5/Ø5.0/Ø6.0	I-System: 15˚/25˚ T-System: 17˚	G/H: 2/3/4 P/H: 7	Bridges
	Temporary Abutment	I-System: Ø4.5 T-System: Ø4.0/Ø4.5	0˚	G/H: 1/3 P/H: 10	-
	Ball Abutment	I-System: Ø3.5 T-System: Ø3.5	N/A	G/H: 1/2/3/4/5/6	Overdentures
	Abutment Screw	I-System: Ø2.3 T-System: Ø2.2/Ø2.3	N/A	I-System: 8.2 T-System: 8.35/10.2	-

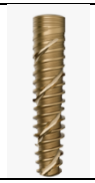
ZENEX Implant System_Long is provided sterile, and valid for 5 years.

Summaries of Technological Characteristics:

ZENEX Implant System_Long 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	Reference Device	Reference Device	Reference Device	Reference Device
Company	Izenimplant Co., Ltd.	Izenimplant Co., Ltd.	OSSTEM Implant Co., Ltd.	OSSTEM Implant Co., Ltd.	S.I.N. - Sistema de Implante Nacional S.A.	Southern Implants (Pty) Ltd
Device Name	ZENEX Implant System_Long	ZENEX Implant System	Osstem Implant System	Osstem Implant System	S.I.N. Dental Implant System	Single Platform SP1 Implant System
510(k) Number	N/A	K211090	K222778	K161604	K221453	K232418
Device Classification Name	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Product Code	DZE	DZE	DZE, NHA	DZE, NHA	DZE, NHA	DZE
Regulation Number	872.3640	872.3640	872.3640	872.3640	872.3640	872.3640
Reason for Predicate/ Reference Device	-	Indications for Use Design of implants and abutments, Materials	Ø3.75 x L18,20 Implant	Ø4.6 X L18 Implant	Implant that can contain Ø4.25 X L18, 20	20, 22 and 24 mm length of Implants
Intended Use	ZENEX Implant System_Long 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 Implants in the 20 mm length when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.	ZENEX 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. Wide Fixture System is intended to be used in the molar region	The Osstem Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide Implant system is intended to be used in the molar region.	The Osstem Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide Implant system is intended to be used in the molar region. Products with diameter or less than	S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. S.I.N. Dental Implant System implants with lengths of 18, 20, 22, or 24 mm may be tilted up to 30°. When used in the mandible or maxilla with implants with lengths of	The Single Platform SPl Implant System is intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. The Single Platform SPl Implant System is intended for immediate function when good primary stability with appropriate occlusal loading is achieved. The Single Platform SPl implants in lengths 20, 22 and 24 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. For the conventional abutment and screws: The Conventional

			Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	18, 20, 22, or 24 mm at an angulation of 30°, a minimum of four implants must be used and must be splinted. When placed in the maxilla with lengths of 18, 20, 22, or 24 mm at angulations between 0° and less than 30°, the S.I.N. Dental Implant System implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. All digitally-designed custom abutments for use with Interface CAD-CAM abutments are to be sent to a S.I.N.-validated milling center for manufacture.	Abutments and Prosthetic Screws are premanufactured prosthetic components directly connected to endosseous dental implants and intended for use in fully edentulous or partially edentulous maxilla and/or mandible to provide support for crowns, bridges or overdentures. For the Titanium Abutment Bases and Passive Abutments: The TIB and Passive Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The TIB and Passive abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: Scan files from desktop scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. For the Temporary Titanium Cylinders: The Southern Implants Temporary Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

Material	Titanium Grade 4 of ASTM F67	Titanium Grade 4 of ASTM F67	Titanium Grade 4 of ASTM F67	Titanium Grade 4 of ASTM F67	Titanium Grade 4 of ASTM F67	Titanium Grade 4 of ASTM F67
Design						–
Structure	- Internal Hex connected - Submerged Fixture - Straight/Taper body shape	- Internal Hex connected - Submerged Fixture - Straight/Taper body shape	- Internal Hex connected	- Internal Hex connected	- Internal Hex connected	Internal Cone and Hex
Diameters (Ø) X Lengths (mm)	Ø3.75X L18, 20 Ø4.25 X L18, 20 Ø4.6 X L18	Ø3.75XL8.5, 10, 11.5, 13, 15 Ø4.25X L7, 8.5, 10, 11.5, 13, 15 Ø4.6X L7, 8.5, 10, 11.5, 13, 15 Ø5.05X L7, 8.5, 10, 11.5, 13, 15 Ø5.4X L7, 8.5, 10, 11.5, 13 Ø5.9X L7, 8.5, 10, 11.5, 13 Ø6.75X L7, 8.5, 10, 11.5, 13	Ø3.75 x L18,20 Ø3.77 x L7 Ø4.25 x L7 Ø4.65 x L7 Ø5.45 x L10,11.5,13,15 Ø5.48 x L8.5 Ø5.5 x L7	Ø3.2 X L8.5,10,11.5,13,15 Ø4.4 X L7,8.5,10,11.5,13,15 Ø4.6 X L18 Ø4.8 X L7,8.5,10,11.5,13,15 Ø5.05 X L18 Ø5.25 X L7,8.5,10,11.5,13,15 Ø6.2 X L6.2,7,8.5,10,11.5,13 Ø7.1 X L6.2,7,8.5,10,11.5,13	Ø3.8 X L18,20,22,24 Ø4.0 X L18,20,22,24 Ø4.5 X L18,20,22,24	Ø3.5 X L8,10,11.5,13,16,18,20 Ø4.0 X L8,10,11.5,13,16,18,20,22,24 Ø5.0 X L8,10,11.5,13,16,18
Surface Treatment	Sand blasting & Acid Etching	Sand blasting & Acid Etching	Sand blasting & Acid Etching	Sand blasting & Acid Etching	Acid Etched	Grit-blasted with a 3.0mm machined section only at coronal end
Sterilization	Gamma Sterilization	Gamma 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	S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when	The Conventional Abutments and Prosthetic Screws are premanufactured prosthetic components directly connected to endosseous dental implants and intended for use in fully edentulous or partially edentulous maxilla and/or mandible to provide support for crowns, bridges or overdentures.

					good primary stability is achieved and with appropriate occlusal loading.	
Shelf Life	5 Years	5 Years	8 Years	8 Years	4 Years	10 Years
Compatible Abutments	Straight and angled abutments	Straight and angled abutments	Straight and angled abutments	Straight and angled abutments	Straight and angled abutments	Straight and angled abutments
Similarities	The ZENEX Implant System_Long have same device characteristics with the Primary devices, ZENEX Implant System (K211090) 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, ZENEX Implant System (K211090) are the indications for Use and fixture length. The reason for the difference of the indications for use between two devices is the subject device system does not include wide fixtures which is intended to be used in the molar region. The whole length of the subject device is longer than the primary Device. To support this discrepancy, K222778, K161604 and K221453 was added, and it covers all range of the fixture diameter and length combination. The Single Platform SPl implants (K232418) in lengths 20, 22 and 24 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Therefore, these differences don't affect the device's fundamental functions, safety and effectiveness.					

Non-clinical testing data:

Below tests were performed on subject device:

- Fatigue Testing according to ISO 14801:2016 under the worst-case scenario

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

- Biocompatibility testing according to ISO 10993-1:2018, 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 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.

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_Long 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. MR Conditional Labeling was leveraged from K211090.

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_Long 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_Long and their predicates are substantially equivalent.