March 16, 2026

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

Re: K253334
Trade/Device Name: ZENEX Implant System_Short (R-System)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: September 30, 2025
Received: February 11, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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
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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)*
K253334

Device Name
ZENEX Implant System_Short (R-System)

Indications for Use *(Describe)*
ZENEX Implant System_Short(R-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.
Short and Wide implants must be splinted to adjacent implants in areas of poor bone quality or high occlusal forces.

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 (R-System)
- 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: 03/13/2026

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

Primary Predicate

- K233163, ZENEX Implant System_Short by Izenimplant Co., Ltd.

Reference Predicates

- K211090, ZENEX Implant System by Izenimplant Co., Ltd.
- K252585, ZENEX Implant System_R-System by Izenimplant Co., Ltd.

Indications for Use:
ZENEX Implant System_Short(R-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.
Short and Wide implants must be splinted to adjacent implants in areas of poor bone quality or high occlusal forces.

Device Description

ZENEX Implant System_Short (R-System) is a thread type implant made of pure titanium according to ASTM F67 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 is a type of fixture, and the dimensions are as follows:

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

Tolerance of dimension shall be within ± 1% range.

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

K number	Abutment Name	Diameter (⌀)	Angulation	Length or Cuff(mm)	Material + Surface Treatment
K252585	Cover Screw	⌀3.5	0˚	P/H: 0.4/1.4/2.0	Ti-6Al-4V ELI
	Healing Abutment	⌀ 4.2/5.2/6.2/7.2/8.0/9.0	0˚	P/H: 3/4/5/6/7/9	Ti-6Al-4V ELI
	Cemented Abutment	⌀4.0/5.0/6.0/7.0	0˚	G/H: 1.8/2.8/3.8/4.8 PH: 5.5/7	Ti-6Al-4V ELI + TiN Coating
	Angled Abutment	⌀4.0/5.0/6.0/7.0	15˚/25˚	G/H: 1.8/2.8/3.8/4.8 P/H: 7	Ti-6Al-4V ELI + TiN Coating
	Temporary Abutment	⌀4.0	0˚	G/H: 0.8/2.8 P/H: 10	Ti-6Al-4V ELI
	Ball Abutment	⌀3.5	0˚	G/H: 0.8/1.8/2.8/3.8/ 4.8/5.8	Ti-6Al-4V ELI
	Multi Abutment	⌀4.8	0˚/17˚/30˚	G/H: 1.3/2.3/3.3/4.3	Ti-6Al-4V ELI
	CCM Cast Abutment	⌀4.0	0˚	G/H: 0.8/2.8 P/H: 10	Co-Cr-Mo Alloy
	FreeMilling Abutment	⌀4.0/5.0/6.0/7.0	0˚	G/H: 1.8/2.8/3.8/4.8 P/H: 9	Ti-6Al-4V ELI + TiN Coating
	Abutment Screw	⌀2.1	0˚	7.7	Ti-6Al-4V ELI
	Multi Angled Abutment Screw	⌀2.05	0˚	6.75	Ti-6Al-4V ELI

Fixture is provided sterile, and valid for 5 years.

Summaries of Technological Characteristics:

ZENEX Implant System_Short(R-System) 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
Company	Izenimplant Co., Ltd.	Izenimplant Co., Ltd.	Izenimplant Co., Ltd.
Device Name	ZENEX Implant System_ Short(R-System)	ZENEX Implant System_Short	ZENEX Implant System_R-System
510(k) Number	N/A	K233163	K252585
Device Classification Name	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Product Code	DZE	DZE	DZE, NHA
Regulation Number	872.3640	872.3640	872.3640
Intended Use	ZENEX Implant System_Short(R-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. Short and Wide implants must be splinted to adjacent implants in areas of poor bone quality or high occlusal forces.	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.	ZENEX Implant System_R-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.
Material	Titanium Grade 4 of ASTM F67	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	- Internal Hex connected - Submerged Fixture - Straight/Taper body shape
Diameters (Ø) X Lengths (mm)	Ø5.05X L6.25 Ø5.4X L6.25 Ø5.9X L6.25 Ø6.75X L6.25	Ø5.05X L6.25 Ø5.4X L6.25 Ø5.9X L6.25 Ø6.75X L6.25	Ø3.85XL8.5, 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, 15 Ø5.9X L7, 8.5, 10, 11.5, 13 Ø6.75X L7, 8.5, 10, 11.5, 13
Surface Treatment	Sand blasting & Acid Etching	Sand blasting & Acid Etching	Sand blasting & Acid Etching
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
Compatible Abutments	Straight and angled abutments	Straight and angled abutments	Straight and angled abutments
Similarities	The ZENEX Implant System_Short (R-System) have same device characteristics with the Primary ZENEX Implant System_Short (K233163) such as the intended use, material, functions, general shape (Design), structure and applied production method are similar.		
Differences	The only difference between the subject device and the primary predicate devices ZENEX Implant System_Short(K233163) is the connection design. To address this difference, the reference device (K252585) was included, which employs the same 5° tapered internal hex connection as the subject device. Therefore, this difference does not raise new questions of safety or 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 devices and leveraged for the subject device:

- Biocompatibility testing on Fixtures made of pure titanium according to ISO 10993-1:2020, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2007, ISO 10993-10:2010 and ISO 10993-11:2006 referenced in K211090
- Gamma sterilization validation Test Report on Fixtures according to ISO 11137-1, ISO 11137-2 and ISO 11137-3 referenced in K211090
- Shelf Life Test on Fixtures according to ASTM F 1980 referenced in K211090
- Bacterial Endotoxin Test Report on Fixtures according to ANSI/AAMI ST72:2011, USP <161>, and USP <85> referenced in K211090

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. The surface area analysis for fixtures was leveraged from K233163.

Sterilization and Shelf Life Testing

The sterilization and shelf life testing for fixtures were conducted on the predicate device, K211090 and leveraged for the subject device. 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

The MR Environment condition is same as the predicate device, K211090. Non-clinical worst-case MRI review was performed to evaluate the metallic ZENEX Implant System_Short (R-System) 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 (R-System) 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 (R-System) and their predicates are substantially equivalent.