January 8, 2026

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

Re: K252585
Trade/Device Name: ZENEX Implant System_R-System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 14, 2025
Received: December 12, 2025

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)*
K252585

Device Name
ZENEX Implant System_R-System

Indications for Use *(Describe)*
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.

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
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Device Information

- Trade Name: ZENEX Implant System_R-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: 01/07/2026

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 Predicates

- K140091, Xpeed AnyRidge Internal Implant System by MegaGen Implant Co., Ltd.
- K181138, IS-III active System by Neobiotech Co., Ltd.
- K203240, AccelX™ Abutments by Integrated Dental Systems
- K210826, Healing Abutment, Cover Screw by Megagen Implant Co., Ltd.
- K231557, ZENEX Implant System_FreeMilling & CCM Cast Abutment by Izen Implant Co., Ltd.

Indications for Use:
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.

Device Description

ZENEX Implant System_R-System 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 MULTI Fixture		Ø 3.85/4.25/4.6/ 5.05/5.4/5.9/6.75	7mm/8.5mm/10mm/ 11.5mm/13mm/15mm	Ti CP4 (ASTM F67)
ZENEX PLUS Fixture		Ø 3.85/4.25/4.6/ 5.05/5.4	7mm/8.5mm/10mm/ 11.5mm/13mm/15mm	

Tolerance of dimension shall be within ± 1% range.

The Abutments are below:

Abutment Name	Diameter (⌀)	Angulation	Length or Cuff(mm)	Material + Surface Treatment
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	0˚	P/H: 3/4/5/6/7/9	Ti-6Al-4V ELI
	⌀8.0		P/H: 3/4/5/6/7	
	⌀9.0		P/H: 3/4/5	
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	0˚	G/H: 1.8/2.8/3.8 P/H: 9	Ti-6Al-4V ELI + TiN Coating
	⌀5.0/6.0/7.0		G/H: 1.8/2.8/3.8 P/H: 8	
Abutment Screw	⌀2.05/2.1	0˚	6.75/7.7	Ti-6Al-4V ELI

Fixture, Cover Screw, Healing Abutment is provided sterile, and valid for 5 years.
Other abutments are provided non-sterile and sterilized by end users.

Summaries of Technological Characteristics:

ZENEX Implant System_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.	MegaGen Implant Co., Ltd
Device Name	ZENEX Implant System_R-System	ZENEX Implant System	Xpeed AnyRidge Internal Implant System
510(k) Number	N/A	K211090	K140091
Device Classification Name	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Product Code	DZE, NHA	DZE, NHA	DZE, NHA
Regulation Number	872.3640	872.3640	872.3640
Indications for Use	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.	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 Xpeed AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Material	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 - Submerged Fixture - Straight/Taper body shape
Diameters (Ø) X Lengths (mm)	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	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	⌀4.0 X 7.7, 9.2, 10.7, 12.2, 14.20, 17.20 ⌀4.4 X 7.7, 9.2, 10.7, 12.2, 14.20, 17.20 ⌀4.9 X 7.7, 9.2, 10.7, 12.2, 14.20, 17.20 ⌀5.4 X 7.7, 9.2, 10.7, 12.2, 14.20, 17.20 ⌀5.9 X 7.7, 9.2, 10.7, 12.2, 14.20, 17.20 ⌀6.4 X 7.9, 9.4, 10.9, 12.4, 14.4 ⌀6.9 X 7.9, 9.4, 10.9, 12.4, 14.4 ⌀7.4 X 7.9, 9.4, 10.9, 12.4, 14.4 ⌀7.9 X 7.9, 9.4, 10.9, 12.4, 14.4

			⌀8.4 X 7.9, 9.4, 10.9, 12.4, 14.4
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_R-System is identical to the Primary Predicate (K211090) in terms of intended use, material, surface treatment, and sterilization method. The overall body design, including the thread profile and diameter/length configurations, is the same as the Primary Predicate. Additionally, the internal connection structure and mechanism are similar to the Reference Device (K140091).		
Differences	The differences between the subject device and the Primary Predicate (K211090) are the internal connection dimensions and shape. The reason for this difference is to adopt the connection interface of the Reference Device (K140091). Although the connection interface differs from the Primary Predicate, the subject device's diameter and length combinations are fully covered by the range of the Primary Predicate. To support the mechanical safety of this connection, fatigue testing was conducted. Therefore, these differences do not affect the device's fundamental functions, safety, and effectiveness.		

Abutment

1) Cover Screw

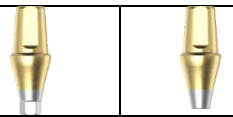
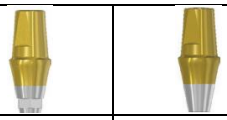
		Subject Device	Primary Predicate
Manufacturer		Izenimplant Co.,Ltd.	Izenimplant Co.,Ltd.
Product Name		ZENEX Implant System_R-System	ZENEX Implant System
510(K) Number		NA	K211090
Classification		Class II	Class II
Design			
Dimension	D	Φ3.5	Φ3.0~3.9
	L	4.8~6.4mm	5~7.3mm
	Angle	0˚	0˚
Material		Ti-6Al-4V ELI	Ti-6Al-4V ELI
Surface		Non-Coating	Non-Coating
Sterilization		Radiation	Radiation
Shelf life		5 years	5 years
SE Discussion		The subject device is similar in intended use, fundamental scientific technology, principle of operation, general design, technology, functions, and materials with the identified Primary Predicate, K211090. The difference between the subject and reference device is dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

2) Healing Abutment

		Subject Device	Primary Predicate	Reference Device
Manufacturer		Izenimplant Co.,Ltd.	Izenimplant Co.,Ltd.	MegaGen Implant Co., Ltd.
Product Name		ZENEX Implant System_R-System	ZENEX Implant System	Healing Abutment, Cover Screw
510(K) Number		NA	K211090	K210826
Classification		Class II	Class II	Class II
Design				
Dimension	D	Φ4.2~9.0	Φ4.3~9.0	Φ4.0~10.0
	P/H	3.0~9.0mm	2.0~9.0mm	4.4~11.35mm
	Angle	0˚	0˚	0˚
Material		Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Surface		Non-Coating	Non-Coating	Non-Coating
Sterilization		Radiation	Radiation	Radiation
Shelf life		5 years	5 years	5 years
SE Discussion		The subject device is substantially equivalent to the Predicate devices (ZENEX Implant System, K211090 and MegaGen Healing Abutment, K210826) in intended use and technological characteristics. All devices are made of titanium (Ti-6Al-4V ELI) non-coated healing abutments intended to be connected to endosseous dental implants for soft-tissue healing during the restorative phase. The subject device shares the same basic design, material, surface treatment, sterilization method, and shelf life as the predicate devices. Dimensional differences are within the predicate ranges: the subject device's diameter (Φ4.2–9.0 mm) and post height (3.0–9.0 mm) fall entirely within the combined ranges of the		

	predicates (Φ4.3–10.0 mm, 2.0–11.35 mm). These differences do not affect safety or effectiveness because they do not alter the mechanical strength, connection integrity, or biological compatibility of the device. Therefore, the subject device is substantially equivalent to the predicate devices in terms of intended use, fundamental scientific technology, and performance characteristics.

3) Cemented Abutment

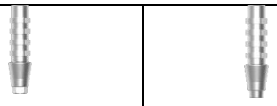
		Subject Device		Primary Predicate		Reference Device	
Manufacturer		Izenimplant Co.,Ltd.		Izenimplant Co.,Ltd.		Neobiotech Co.,Ltd.	
Product Name		ZENEX Implant System_R-System		ZENEX Implant System		IS-III active System	
Abutment Name		Cemented Abutment		Cemented Abutment		Cemented Abutment	
510(K) Number		NA		K211090		K181138	
Classification		Class II		Class II		Class II	
Design							
		Hex	Non-Hex	Hex	Non-Hex	Hex	Non-Hex
Dimension	D	Φ4.0~7.0		Φ4.5~6.5		Φ4.0~7.0	
	G/H	1.8~4.8mm		1.0~7.0mm		1.0~5.0mm	
	P/H	5.5/7.0mm		4.0~7.0mm		4.0/7.0mm	
	Angle	0˚		0˚		0˚	
Material		Ti-6Al-4V ELI		Ti-6Al-4V ELI		Ti-6Al-4V ELI	
Surface		Partial TiN coated in upper		Partial TiN coated in upper		Partial TiN coated in upper	
Sterilization		End User Sterilization		End User Sterilization		End User Sterilization	
SE Discussion		The subject device is similar in intended use, fundamental scientific technology, principle of operation, general design, technology, functions, dimension and materials with the primary predicate, K211090. The difference between the subject and primary predicate K211090 is dimensions of the device. To support this discrepancy, K181138 was added; therefore, it is substantial equivalent.					

4) Angled Abutment

		Subject Device	Primary Predicate		Reference Device
Manufacturer		Izenimplant Co.,Ltd.	Izenimplant Co.,Ltd.		Integrated Dental Systems LLC
Product Name		ZENEX Implant System_R-System	ZENEX Implant System		AccelX™ Abutments
510(K) Number		NA	K211090		K203240
Classification		Class II	Class II		Class II
Design					
		Hex	Hex	Non-Hex	Hex
Dimension	D	Φ4.0~7.0	Φ4.5~5.7		Φ4.0~7.0
	Cuff	1.8/2.8/3.8/4.8mm	1.8/2.8/3.8mm		2 mm – 5 mm
	Angle	15˚and 25˚	15˚ and 25˚		15˚ and 25˚
Material		Ti-6Al-4V ELI	Ti-6Al-4V ELI		Ti-6Al-4V ELI
Surface		Partial TiN coated in upper	Partial TiN coated in upper		Unknown
Sterilization		End User Sterilization	End User Sterilization		End User Sterilization

SE Discussion	The subject device is substantially equivalent to the primary predicate (ZENEX Implant System, K211090, and AccelXTm Abutments, K203240) in intended use and technological characteristics. All devices are titanium alloy (Ti-6Al-4V ELI) angled abutments intended to connect to endosseous dental implants to support prosthetic restorations. The subject and predicate devices share the same intended use, basic geometry, angles (15° and 25°), material, sterilization method, and overall configuration. The subject device provides hex connection geometry identical to predicate K203240 and similar cuff height range (1.8–4.8 mm) that is fully encompassed within the predicate ranges (1.8–5.0 mm). The partial TiN coating applied to the upper portion of the subject device is identical to the manufacturer's existing predicate (K211090) and does not alter the biological or mechanical performance of the abutment. Therefore, the subject device is substantially equivalent to the predicate devices in intended use, fundamental scientific technology, and performance characteristics.

5) Temporary Abutment

		Subject Device		Primary Predicate	
Manufacturer		Izenimplant Co.,Ltd.		Izenimplant Co.,Ltd.	
Product Name		ZENEX Implant System R-System		ZENEX Implant System	
510(K) Number		NA		K211090	
Classification		Class II		Class II	
Design					
		Hex	Non-Hex	Hex	Non-Hex
Dimension	D	Φ4.0		Φ4.0~4.5	
	G/H	0.8/2.8mm		1.0~7.0mm	
	P/H	10.0mm		10.0mm	
	Angle	0˚		0˚	
Material		Ti-6Al-4V ELI		Ti-6Al-4V ELI	
Surface		Non-Coating		Non-Coating	
Sterilization		End User Sterilization		End User Sterilization	
SE Discussion		The subject device is similar in intended use, fundamental scientific technology, principle of operation, general design, technology, functions, diameter, and materials with the identified primary predicate. The subject device includes shorter length implant such as 0.8mm, however, this abutment is for temporary use; therefore, it is substantial equivalent.			

6) Ball Abutment

		Subject Device	Primary Predicate
Manufacturer		Izenimplant Co.,Ltd.	Izenimplant Co.,Ltd.
Product Name		ZENEX Implant System_R-System	ZENEX Implant System
510(K) Number		NA	K211090
Classification		Class II	Class II
Design			
Dimension	D	Φ3.5	Φ3.5
	Length	8.9~13.9mm	9.15 ~ 14.65mm
	Head Diameter	2.25	2.25
	Head Length	3.35	3.35
	Angle	0˚	0˚
Material		Ti-6Al-4V ELI	Ti-6Al-4V ELI
Surface		Non-Coating	Non-Coating
Sterilization		End User Sterilization	End User Sterilization
SE Discussion		The subject device is similar in intended use, fundamental scientific technology, principle of operation, general design, technology, functions, and materials with the identified primary predicate, K211090. The difference between the subject and primary predicate, K211090 is diameter of the device.	

7) Multi Abutment

		Subject Device		Primary Predicate	
Manufacturer		Izenimplant Co.,Ltd.		Izenimplant Co.,Ltd.	
Product Name		ZENEX Implant System_R-System		ZENEX Implant System	
510(K) Number		NA		K211090	
Classification		Class II		Class II	
Design					
		Hex	Non-Hex	Hex	Non-Hex
Dimension	D	Φ4.8		Φ4.8	
	Angle	0˚, 17 ˚, 30 ˚		0˚, 17 ˚, 30 ˚	
Material		Ti-6Al-4V ELI		Ti-6Al-4V ELI	
Surface		Non-Coating		Non-Coating	
Sterilization		End User Sterilization		End User Sterilization	
SE Discussion		The subject device is similar in intended use, fundamental scientific technology, principle of operation, general design, technology, functions, and materials with the identified primary predicate, K211090. There is no difference between two devices; therefore, it is substantially equivalent.			

8) CCM Cast Abutment

		Subject Device		Reference Device	
Manufacturer		Izenimplant Co.,Ltd.		Izenimplant Co.,Ltd.	
Product Name		ZENEX Implant System_R-System		ZENEX Implant System_FreeMilling & CCM Cast Abutment	
510(K) Number		NA		K231557	
Classification		Class II		Class II	
Design		 Hex	 Non-Hex	 Hex	 Non-Hex
Dimension	D	Φ4.0		Φ4.0	
	Length	12.5/13/14.5/15mm		14.5/15mm	
	Angle	0˚		0˚	
Material		Co-Cr-Mo Alloy		Co-Cr-Mo Alloy	
Surface		No Coating		No Coating	
Sterilization		End User Sterilization		End User Sterilization	
SE Discussion		The subject device is similar in intended use, fundamental scientific technology, principle of operation, general design, technology, functions, diameter and materials with the reference device, K231557. The difference between the subject device and predicate is lengths. Since it is the case abutment, the different length does not affect device's fundamental functions and safety. Therefore, it is substantial equivalent.			

9) FreeMilling Abutment

		Subject Device	Reference Device	
Manufacturer		Izenimplant Co.,Ltd.	Izenimplant Co.,Ltd.	
Product Name		ZENEX Implant System_R-System	ZENEX Implant System_FreeMilling & CCM Cast Abutment	
510(K) Number		NA	K231557	
Classification		Class II	Class II	
Design		 Hex	 Hex	 Non-Hex
Hand Milling Only		Yes	Yes	
Dimension	D	Φ4.0	Φ4.0~7.0	
	G/H	1.8/3.8mm	1.3/3.8	
	P/H	9.0mm	8.0/9.0mm	
	Angle	0˚	0˚	
Material		Ti-6Al-4V ELI	Ti-6Al-4V ELI	
Surface		Partial TiN coated in upper	Partial TiN coated in upper	
Sterilization		End User Sterilization	End User Sterilization	
SE Discussion		The subject device has the same intended use, material, technology, and general design as the reference device (K231557). The only difference is the dimensional range, as the reference device covers a wider range in diameter and length. These variations do not affect the device's function or safety. Therefore, the subject device is considered substantially equivalent to the predicate device.		

10) Abutment Screw

		Subject Device	Primary Predicate
Manufacturer		Izenimplant Co.,Ltd	Izenimplant Co.,Ltd.
Product Name		ZENEX Implant System_R-System	ZENEX Implant System
510(K) Number		NA	K211090
Classification		Class II	Class II
Design			
Dimension	D	Φ2.0	Φ2.0
	Length	8.9mm	10.2mm
Material		Ti-6Al-4V ELI	Ti-6Al-4V ELI
Surface		No Coating	No Coating
Sterilization		N/A	N/A
SE Discussion		The subject device is similar in intended use, fundamental scientific technology, principle of operation, general design, technology, functions, diameter, and materials with the identified primary predicate, K211090. The difference between the subject and reference device is length of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

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 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
- End User Sterilization Validation Test Report for Abutments made with Ti-6Al-4V ELI according to ANSI/AAMI ST79, ISO 17665-1,-2, ISO 11737-1,-2, and ISO 11138-1 referenced in K211090 referenced in K211090
- End User Sterilization Validation Test Report on subject CCM Cast Abutments according to ANSI/AAMI ST79, ISO 17665-1,-2, ISO 11737-1,-2, and ISO 11138-1 referenced in K211090
- Biocompatibility Testing on Abutment made of Ti-6Al-4V ELI and TiN Coated ELI according to ISO 10993-1:2018, ISO 10993-5:2009 and ISO 10993-12:2021 referenced in K211090
- Biocompatibility testing on CCM material according to ISO 10993-1:2018, ISO 10993-5:2009 and ISO 10993-12 : 2021 referenced in K231557

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 TiN coating for abutments was also referenced from K211090.

Sterilization and Shelf Life Testing

The sterilization and shelf life testing for fixtures and abutments 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 for fixture made with pure titanium and abutments made with Ti-6Al-4V ELI and K231557 for Ti-6Al-4V ELI with TiN Coated 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_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_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_R-System and their predicates are substantially equivalent.