July 31, 2023

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

Re: K230630
Trade/Device Name: ZENEX Implant System_Narrow
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 5, 2023
Received: July 5, 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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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)*

K230630

Device Name

ZENEX Implant System_Narrow

Indications for Use *(Describe)*

The ZENEX Implant System_Narrow (3.0, 3.2mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
The implants may be restored immediately
1) with a temporary prosthesis that is not in functional occlusion,
2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or
3) for denture stabilization using multiple implants in the anterior mandible and maxilla.
The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary

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Device Information

- Trade Name: ZENEX Implant System_Narrow
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3640
- Date prepared: 07/28/2023

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

Primary Predicate
K161244, s-Clean OneQ-SL Narrow Implant System manufactured by Dentis Co., Ltd.

Reference Device
K161604, OSSTEM Implant System by Osstem Implant Co., Ltd.
K161987, UF(II) Narrow Implant System - Fixture, UF(II) Narrow Implant System – Suprastructure by DIO Corporation
K172100, URIS OMNI System by TruAbutment Korea Co.,Ltd.
K182081, JDentalCare Implant System JDIcon by J Dental Care S.R.L.
K182194, UV Active Implant System by DIO Corporation
K190849, IS-III active System_S-narrow Type by Neobiotech Co., Ltd.
K211090, ZENEX Implant System by Izenimplant Co., Ltd.
K220079, Magicore Narrow System by InnobioSurg Co., Ltd.

Indications for Use
The ZENEX Implant System_Narrow (3.0, 3.2mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
The implants may be restored immediately
1) with a temporary prosthesis that is not in functional occlusion,
2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or
3) for denture stabilization using multiple implants in the anterior mandible and maxilla.
The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.

Device Description:

The fixtures and abutments in this system are below:

1) Fixture
   - ZENEX MULTI Fixture
   - ZENEX PLUS Fixture

2) Abutment
   - Cover Screw
   - Healing Abutment
   - Cemented Abutment (Hex, Non-Hex)
   - Angled Abutment (Hex, Non-Hex)
   - Temporary Abutment (Hex, Non-Hex)
   - FreeMilling Abutment (Hex, Non-Hex)
   - CCM Cast Abutment (Hex, Non-Hex)
   - Abutment Screw

An endosseous dental implant is a device made of a material such as Ti 6AL 4V Eli (Conforming to ASTM Standard F-136). The ZENEX Implant System_Narrow consists of dental implants, Abutments, and screws for use in one or two-stage dental implant placement and restorations.
The implant-Abutment connection is tight and precise fitting with internal hex and Morse taper bevel.
The surface of the ZENEX MULTI and PLUS Fixtures are treated with SLA(sand-blasted, large-grit, acid-etched).

ZENEX Plus Fixture is compatible with the subject abutments as below:

Fixture	Compatible Abutment	Abutment Diameter	Abutment Length (mm)	Abutment Angle
ZENEX PLUS Fixture Ø 3.0 X 10, 11.5, 13, 15mm	Cover Screw	Ø2.6	4.0	0˚
	Healing Abutment	Ø4.0	7/8/9/10/11/13	0˚
	Cemented Abutment	Ø4.0	Hex: 9.5/10.5/11.5/11/11.5/12/12.5/13/14 Non-Hex: 9/10/10.5/11/11.5/12/12.5/13.5	0˚
	Angled Abutment	Ø4.0	Hex:11/13 Non-Hex: 10.5/12.5	15˚
	Temporary Abutment	Ø4.0	Hex: 13/15 Non-Hex: 12.5/14.5	0˚
	FreeMilling Abutment	Ø4.0	Hex: 13/15 Non-Hex: 12.5/14.5	0˚
	CCM Cast Abutment	Ø4.0	Hex: 13/15 Non-Hex: 12.5/14.5	0˚

ZENEX MULTI Fixture is compatible with the abutments cleared in K211090 except cover screw as below:

Fixture	Compatible Abutment	Abutment Diameter	Abutment Length (mm)	Abutment Angle
ZENEX MULTI Fixture Ø 3.2 X 8.5, 10, 11.5, 13, 15mm	Cover Screw (Subject device)	Ø2.9/ Ø3.2	4.5/5.5/6.1	0˚
	Healing Abutment	Ø4.3/ Ø4.8	7.5/8.5/9.5/11.5/13.5	0˚
	Cemented Abutment	Ø4.0/ Ø4.5	Hex:9.08/10.08/10.58/11.08/11.58/12.08/12.58/ 13.08/13.58/14.08/14.58/15.08/15.58/16.08/16.58 Non-Hex:8.48/9.48/9.98/10.48/10.98/11.48/ 11.98/12.48/12.98/13.48/13.98/14.48/14.98/15.98	0˚
	Temporary Abutment	Ø4.0	Hex:13.58/15.58 Non-Hex: 12.98/14.98	0˚

Below are the abutment's features:

Abutments	Uses	Surface Treatment
Cover Screw	The cover Screw is used during the healing period prior to restorations and maintain the shape of the gum	Non
Healing Abutment	The Abutment is used during the healing period prior to restorations and maintain the shape of the gum.	Non
Cemented Abutment (Hex, Non-Hex)	The Abutment is connected with fixture, and it supports prosthesis which restores tooth function.	Partial TiN coated in upper
Angled Abutment (Hex, Non-Hex)	The Abutment is connected with fixture, and it supports prosthesis which restores tooth function.	Partial TiN coated in upper
Temporary Abutment (Hex, Non-Hex)	The Abutment is used by removing the healing abutment as an abutment for making temporary prostheses	Non
FreeMilling Abutment (Hex, Non-Hex)	The Abutment is connected with fixture, and it supports prosthesis which restores tooth function. The FreeMilling Abutment is only intended to be modified by hand-milling.	Partial TiN coated in upper
CCM Cast Abutment (Hex, Non-Hex)	It is used when there are restrictions on the prosthesis production because of path, aesthetics, and space of fixture. Production the prosthesis by casting with dental alloy after wax up with desired shape	Non
Abutment Screw	Connection body to connect abutment to fixture.	Non

The subject fixture, cover screw and healing abutment are provided sterile.
Other abutments are provided non-sterile and packaged separately. The abutments should be sterilized before use by End User sterilization.

Materials:

- ZENEX Implant Narrow Fixtures and abutments are made of Ti-6Al-4V Eli
- CCM Cast Abutment is made of Co-Cr-Mo Alloy

Summaries of Technological Characteristics & Substantial Equivalence Discussion

Fixture – ZENEX MULTI Fixture and ZENEX PLUS Fixture

	Subject Device	Primary Predicate	Reference Device	Reference Device
Manufacturer	Izenimplant Co.,Ltd	Dentis Co., Ltd.	InnoBioSurg Co.,Ltd	Neobiotech Co., Ltd
Product Name	ZENEX Implant System_Narrow	s-Clean OneQ-SL Narrow Implant System	Magicore Narrow System	IS-III active System_ S-Narrow Type
510(K) #	K230630	K161244	K220079	K190849
Classification	Class II	Class II	Class II	Class II
Design				
Connection	Internal Hex	Internal Hex	Internal Hex	Internal Hex
Endosseous Implant	Tapered, macro threads	Tapered, macro threads	Tapered, macro threads	Tapered, macro threads
Surgical Technique	1 and 2 stage, self-tapping	1 and 2 stage, self-tapping	1 and 2 stage, self-tapping	1 and 2 stage, self-tapping
Diameter and Length(mm)	• Φ3.0mm X10,11.5,13,15 mm • Φ3.2mm X 8.5,10,11.5,13,15 mm	Φ3.0, 3.3mm X10,12,14mm	Φ3.0mm 11,13,15mm	Φ3.2mm 8.5/10.0/11.5/13.0/15.0
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Surface	Sandblasted and acid-etched	Sandblasted and acid-etched	Sandblasted and acid-etched	Sandblasted and acid-etched
Sterilization	Radiation	Radiation	Radiation	Radiation
Shelf life	5 years	8 years	8 years	5 years
Indications for use	The ZENEX Implant System_Narrow (3.0, 3.2mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately	The s-Clean OneQ-SL Narrow Implant System (3.0, 3.3mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion,	The Magicore Narrow System (3.0, 3.5mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for	The IS-III active System_S-narrow Type is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth,

	1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.	2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.	multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.	in order to restore the patient's chewing function. The IS-III active System_S-narrow Type is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
SE Discussion	The ZENEX Implant System_Narrow has similar device characteristics with the Primary predicate, K161244 such as intended use, functions, material, surface treatment, fixture diameter, structure and applied production method. The difference between the subject device and primary predicate are device design, 15mm length fixtures, Ø3.2X8.5mm and shelf life. The difference of the device design of both devices does not affect device's fundamental functions and safety. To support the 15mm length for each diameter, K220079 and K190849 were added as reference device. To support the difference of the Ø3.2X8.5mm and shelf life, the K190849 was added. Any differences do not raise different questions of safety and effectiveness than the primary predicate; therefore, it is substantial equivalent.			

Abutment

1) Cover Screw

		Subject Device	Reference Device
Manufacturer		Izenimplant Co.,Ltd	Izenimplant Co.,Ltd
Product Name		ZENEX Implant System_Narrow	ZENEX Implant System
510(K) Number		K230630	K211090
Classification		Class II	Class II
Design			
Dimension	D	Φ2.6~3.2	Φ3.0~3.9
	L	4~6.1mm	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 reference device, K211090. The difference between the subject and reference device is dimension of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

2) Healing Abutment

		Subject Device	Reference Device	Reference Device
Manufacturer		Izenimplant Co.,Ltd	Izenimplant Co.,Ltd	Osstem Implant Co., Ltd
Product Name		ZENEX Implant System_Narrow	ZENEX Implant System	Osstem Implant System
510(K) Number		K230630	K211090	K161604
Classification		Class II	Class II	Class II
Design				
Dimension	D	Φ4.0	Φ4.3~9.0	Φ4.0
	P/H	3.0~9.0mm	2.0~9.0mm	3.0~9.0mm
	Angle	0˚	0˚	0˚
Material		Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Surface		Non-Coating	Non-Coating	TiN Coating
Sterilization		Radiation	Radiation	Radiation
Shelf life		5 years	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 reference device, K161604. The difference between the subject and reference device, K161604 is surface treatment. To support the discrepancy, K211090 was added. Therefore, it is substantial equivalent.		

3) Cemented Abutment

		Subject Device		Reference Device	
Manufacturer		Izenimplant Co.,Ltd		Neobiotech Co., Ltd	
Product Name		ZENEX Implant System_Narrow		IS-III active System_S-Narrow Type	
Abutment Name		Cemented Abutment		IS Shapable Abutment	
510(K) Number		K230630		K190849	
Classification		Class II		Class II	
Design					
		Hex	Non-Hex	Hex	Non-Hex
Dimension	D	Φ4.0		Φ3.5/4.0	
	G/H	2.0-5.0mm		2.0-5.0mm	
	P/H	5.5/7.0mm		5.5/7.0mm	
	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 is similar in intended use, fundamental scientific technology, principle of operation, general design, technology, functions, dimension and materials with the identified reference device, K190849. The design of the subject and reference device is slightly different. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.			

4) Angled Abutment

		Subject Device		Reference Device	
Manufacturer		Izenimplant Co.,Ltd		DIO Corporation	
Product Name		ZENEX Implant System_Narrow		UV Active Implant System	
510(K) Number		K230630		K182194	
Classification		Class II		Class II	
Design					
		Hex	Non-Hex	Hex	Non-Hex
Dimension	D	Φ4.0		Φ4.0/4.5/5.5	
	G/H	2.0/4.0mm		1.5/2.0/3.0/4.0/5.0	
	Angle	15˚		Ø4.0 – 15 ˚ Ø4.5 – 15, 25 ˚ Ø5.5 – 15, 25 ˚	
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 is similar in intended use, fundamental scientific technology, principle of operation, general design, technology, functions, and materials with the identified reference device, K182194. The difference between the subject device and K182194 is design and dimensions. The design of the subject and reference device is slightly different, and it does not affect device's fundamental functions and safety. The dimension of the subject device is in range of the dimension of the predicate. Therefore, it is substantial equivalent.			

5) FreeMilling Abutment

		Subject Device		Reference Device		Reference Device	
Manufacturer		Izenimplant Co.,Ltd		DIO Corporation		J DENTALCARE®S.R.L.	
Product Name		ZENEX Implant System_Narrow		UV Active Implant System		JDIcon® Implant System	
Abutment Name		FreeMilling Abutment		Mill abutment		GP Abutment	
510(K) Number		K230630		K182194		K182081	
Classification		Class II		Class II		Class II	
Design							
		Hex	Non-Hex	Hex	Non-Hex	Hex	Non-Hex
Hand Milling Only		Yes		Yes		Yes	
Dimension	D	Φ4.0		Φ 3.2/4.0		Φ 3.2/4.0	
	G/H	2.0/4.0mm		1.5mm		1.5mm	
	Angle	0˚		0˚		0˚	
Material		Ti-6Al-4V ELI		Titanium Grade4		Ti-6Al-4V ELI	
Surface		Partial TiN coated in upper		Partial TiN coated in upper		No Coating	
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 with the identified reference device, K182194. The difference between the subject device and K182194 is design, dimensions and materials. To support this material difference, K182081 was added. The design of the subject and reference device is slightly different, and it does not affect device's fundamental functions and safety. The dimension of the subject device is in range of the dimension of the predicate. Therefore, it is substantial equivalent.					

6) CCM Cast Abutment

		Subject Device		Primary Predicate	
Manufacturer		Izenimplant Co.,Ltd		Dentis Co.,Ltd	
Product Name		ZENEX Implant System_Narrow		s-Clean One-Q-SL Narrow Implant System	
510(K) Number		K230630		K161244	
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 primary predicate, K161244. 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.			

7) Temporary Abutment

		Subject Device		Reference Device
Manufacturer		Izenimplant Co.,Ltd		TruAbutment Korea Co.,Ltd
Product Name		ZENEX Implant System_Narrow		URIS OMNI System
510(K) Number		K230630		K172100
Classification		Class II		Class II
Design				
		Hex	Non-Hex	
Dimension	D	Φ4.0		Φ3.7/ Φ4.3mm
	P/H	10.0mm		10.0mm
	Angle	0˚		0˚
Maximum duration		Placed less than six months and out of occlusion		Placed less than six months and out of occlusion
Material		Ti-6Al-4V ELI		Ti-6Al-4V ELI
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, and materials with the identified reference device, K172100. The design of the subject and reference device is slightly different, and it does not affect device's fundamental functions and safety. The dimension of the subject device is in range of the dimension of the predicate. Therefore, it is substantial equivalent.		

8) Abutment Screw

		Subject Device	Reference Device
Manufacturer		Izenimplant Co.,Ltd	Neobiotech Co., Ltd
Product Name		ZENEX Implant System_Narrow	IS-III active System_S-Narrow Type
510(K) Number		K230630	K190849
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		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 reference device. 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 Data:

Below tests were performed on subject device:

- Bacterial Endotoxin Testing on Fixture according to USP <85>
- Fatigue Testing under the worst-case scenario according to ISO 14801:2016

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

- Sterilization Validation Testing for Healing Abutment provided sterile according to ISO 11137-1 and ISO 11137-2 referenced in K211090
- Shelf-Life Testing on Fixture and Healing Abutment according to ASTM F1980 referenced in K211090
- End User Sterilization Validation Testing for Ti-6Al-4V ELI and CCM material according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1 referenced in K211090
- Biocompatibility testing on abutments according to ISO 10993-1:2018 referenced in K211090

The surface modification information with SLA (sand-blasted, large-grit, acid-etched) was provided. To compare surface modification between the subject and predicate device, K211090, surface roughness, surface composition analysis, and SEM imaging were provided, and it demonstrate the substantial equivalence.

In accordance with the Association for the AAMI ST72:2002/R2010, Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing (AAMI ST72), validation cycle of endotoxin will be processed and managed.

The Fatigue Testing was performed under the worst-case scenario according to ISO 14801:2016.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the ZENEX Implant System_Narrow 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.

Clinical testing was not necessary to establish substantial equivalency of the device.

Conclusion

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