April 13, 2022

Izenimplant Co., Ltd.
% Milly Milly
Official Correspondent of Izenimplant Co., Ltd.
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
REPUBLIC OF KOREA

Re: K211090
Trade/Device Name: ZENEX Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 10, 2022
Received: March 14, 2022

Dear Milly Milly:

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
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)*
K211090

Device Name
ZENEX Implant System

Indications for Use *(Describe)*
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

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

K211090

Date: April 13, 2022

1. Applicant / Submission Sponsor

Izenimplant Co., Ltd.
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2. Submission Correspondent

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Email: milly@kmcerti.com

3. Device Identification

- Trade/Proprietary Name: ZENEX Implant System
- Classification Name: Root-form endosseous implant
- Common Name: Dental Implant System
- Classification Regulation: 21CFR 872.3640
- Product Code: DZE, NHA
- Device Class: Class II
- Review Panel: Dental

4. Predicate Devices

4.1 Primary Predicate

No.	K Number	Manufacturer	Trade Name
1	K161604	OSSTEM Implant Co., Ltd.	Osstem Implant System

4.2 Reference Device

No.	K Number	Manufacturer	Trade Name
1	K182091	OSSTEM Implant Co., Ltd	Osstem Abutment System
2	K181138	Neobiotech Co., Ltd.	IS-III Active System

5. Device Description

ZENEX Implant System is consisted with ZENEX Fixtures (ZENEX MULTI Fixture and ZENEX PLUS Fixture) and Izenimplant Abutment System. The implant fixtures come in two unique systems, the I-System and the T-System, each with their own abutment compatibilities.

1) ZENEX Fixtures

This product is a dental implant which is put into the alveolar bone in order to support, or maintain the prosthetic tooth or denture when a patient's teeth are partially or totally lost. To enhance the osseointegration with the alveolar bone, this titanium dental implant is treated with SLA surface.

As a dental implant which is put into the alveolar bone to support the dental prostheses such as the artificial teeth which are used to rehabilitate a patient's masticatory function, it is used as a substructure which is implanted into the human body.

This product is a dental implant fixture to be inserted into the bone and is intended to be used in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations. It is connected to the upper structure with Internal Hex fastening structure. In the surface treatment, machined surface was sanded with alumina (Al_2O_3) powder and acid (hydrochloric acid, sulfuric acid) etching process was applied to the surface to increase the contact surface with the bone.

ZENEX PLUS is a design that adds a micro-groove at the collar compared to ZENEX MULTI.

2) Izenimplant Abutment System

Izenimplant Abutment System is compatible with the ZENEX Fixtures (ZENEX MULTI Fixture, ZENEX PLUS Fixture). Izenimplant Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Separate sets of abutments are presented for compatibility with each I-System and T-System. Some subject abutments undergo Titanium Nitride (TiN) coating.

Dental Abutment System is similar to other commercially available products based on the intended use, technology used, claims, material composition employed and performance characteristics.

Especially, the Izenimplant Abutment System is consisted following;

Category	Item	Description
Abutment	Cemented Abutment	It is an abutment for making cement and combination maintenance-type prosthetics by taking a fixture level impression. It is an abutment for making cement and combination-retaining prosthesis by taking a fixture level impression.
	Angled Abutment I-System – 15°/25°	It is an abutment for making cement and combination maintenance-type prosthetics by

	T-System – 17°	taking a fixture level impression. It is an abutment for making cement and combination-retaining prosthesis by taking a fixture level impression.
	Ball Abutment	It is an abutment for making cement and combination maintenance-type prosthetics by taking a fixture level impression
	Multi Abutment (Multi Straight Abutment) (Multi Angled Abutment, 17°/30°)	It is an abutment used when manufacturing screw retaining prosthesis in multiple cases.
	Temporary Abutment	Temporary Abutment is used by removing the healing abutment as an abutment for making temporary prostheses
	Healing Abutment	Healing is used during the healing period prior to restorations and maintain the shape of the gum.
	Cover Screw	Cover Screw is used during the healing period prior to restorations and maintain the shape of the gum
	Multi Ti Link Cylinder	It is an abutment for manufacturing combination maintenance type prosthesis by taking an abutment level impression.
	Multi Temporary Cylinder	This product is an abutment for casting. Use temporarily
	Multi CCM Cast Cylinder	It is an abutment for manufacturing combination maintenance type prosthesis by taking an abutment level impression.
Component	Abutment Screw	It is used to fix the abutment to the fixture.
	Ball Abutment Component (Cap, Retainer and O-ring)	It is a product that is inserted into the overdenture, and it is installed on the ball abutment to support the overdenture.
	Multi Angled Abutment Screw	It is used to fix the Multi Angled Abutment to the fixture.
	Multi Cylinder Screw	It is fixed to cylinder
	Multi Healing Cap	This product protects the Multi Abutments during healing phase

5. Indications for Use

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

6. Substantial Equivalence

6.1 Comparison Table

Comparison of the technical characteristics of the subject device and predicate devices is shown in the Table of Substantial Equivalence Below.

6.1.1 Indications for use

The Indications for Use Statements are compared in the tables below. It can be seen that the Indications for Use Statements of the Subject and Primary Predicate devices, including reference devices, are similar as support for dental restorations.

Although the subject device does not have products with diameter that are less than 3.75mm or products that are indicated for use in lateral incisor, the test results of bench test of the rest of the products demonstrated that this difference does not raise new safety or effectiveness concerns for the provided intended use.

Subject Device (ZENEX Implant System)	**Primary Predicate Device (K161604)**	**Secondary Predicate Device (K182091)**	**Third Predicate Device (K181138)**
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 Fixture System is intended to be used in the molar region. Products with diameter of less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible.	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The IS-III active System is indicated for use in Halfly or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate Abutment support for fixed bridgework.

6.1.2 Technical

1) ZENEX Fixture

Descriptive Information	Subject Device	Primary Predicate Device
Manufacturer	Izenimplant, Co., Ltd.	OSSTEM Implant Co., Ltd.
Product Name	ZENEX MULTI Fixture, ZENEX PLUS Fixture	Osstem Implant System
510(K) Number	-	K161604
Product Code / Regulation	DZE / 21CFR 872.3640	DZE / 21CFR 872.3640
Structure	- Internal Hex connected - Submerged Fixture - Straight/Taper body shape	- Internal Hex connected - Submerged Fixture - Straight/Taper body shape
Body Diameter and Length (mm)	Mini Ø 3.75 x L8.5, 10, 11.5, 13, 15 Regular Ø 4.25 x L7, 8.5, 10, 11.5, 13, 15 Ø 4.6 x L7, 8.5, 10, 11.5, 13, 15 Wide Ø 5.05 x 7, 8.5, 10, 11.5, 13, 15 Ø 5.4 x 7, 8.5, 10, 11.5, 13, Ø 5.9 x 7, 8.5, 10, 11.5, 13 Ø 6.75 x 7, 8.5, 10, 11.5, 13	 Ø 3.2 x L8.5, 10, 11.5, 13. 15 Ø 4.4 x L7, 8.5, 10, 11.5, 13, 15 Ø 4.8 x 7, 8.5, 10, 11.5, 13, 15 Ø 5.25 x 7, 8.5, 10, 11.5, 13, 15 Ø 6.2 x 7, 8.5, 10, 11.5, 13 Ø 7.1 x 7, 8.5, 10, 11.5, 13
Material	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)
Surface	Sandblasted and acid-etched	Sandblasted and acid-etched
Sterilization	Radiation	Radiation
Shelf Life	5 years	8 years

2) Cemented Abutment

-		Subject Device	Predicate Device
Manufacturer		Izenimplant Co., Ltd.	Neobiotech Co., Ltd.
Device Name		ZENEX Implant System	IS-III active System
510(k) Number		-	K181138
Classification		Class II	Class II
Design			
Connection Type		Hex, Non-Hex	Hex, Non-Hex
Dimension	**D(Ø)**	4.5 ~ 6.5	4.0 ~ 7.0
	G/H (mm)	1.0 ~ 7.0	1.0 ~ 5.0
	P/H (mm)	4.0 ~ 7.0	4.0 ~ 7.0
	Angle	0°	0°
Surface Treatment		Partial TiN coated in upper	Partial TiN coated in upper
Sterilization		Non-Sterile	Non-Sterile
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)

3) Angled Abutment

-		Subject Device	Predicate Device
Manufacturer		Izenimplant Co., Ltd.	Neobiotech Co., Ltd.
Device Name		ZENEX Implant System	IS-III active System
510(k) Number		-	K181138
Classification		Class II	Class II
Design			
Connection Type		Hex, Non-Hex	Hex, Non-Hex
Dimension	**D(Ø)**	4.5 ~ 5.7	4.5 ~ 6.0
	G/H (mm)	2.0 ~ 4.0	2.0 ~ 4.0
	P/H (mm)	7.0	7.5 ~ 8.0
	Angle	15° ~ 25°	15° ~ 25°
Surface Treatment		Partial TiN coated in upper	Partial TiN coated in upper
Sterilization		Non-Sterile	Non-Sterile
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)

4) Ball Abutment

-		Subject Device	Predicate Device
Manufacturer		Izenimplant Co., Ltd.	Neobiotech Co., Ltd.
Device Name		ZENEX Implant System	IS-III active System
510(k) Number		-	K181138
Classification		Class II	Class II
Design			
Connection Type		Non-Hex (Screw Type)	Non-Hex (Screw Type)
Dimension	**D(Ø)**	3.5	3.5
	Length (mm)	9.15 ~ 14.65	11.1 ~ 14.1
	Head Diameter (Ø)	2.25	2.4
	Head Length (mm)	3.35	1.0 ~ 4.0
	Angle	0°	0°
Surface Treatment		Non-Coating	Non-Coating
Sterilization		Non-Sterile	Non-Sterile
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)

5) Multi Abutment

-		Subject Device	Predicate Device
Manufacturer		Izenimplant Co., Ltd.	Osstem Implant Co., Ltd.
Device Name		ZENEX Implant System	Osstem Abutment System
510(k) Number		-	K182091
Classification		Class II	Class II
Design			
Connection Type		Hex, Non-Hex	Hex, Non-Hex
Dimension	**D(Ø)**	4.8	4.9
	Angle	0°, 17°, 30°	0°, 17°, 30°
Surface Treatment		Non-Coating (Angled Abutment)	Non-Coating (Angled Abutment)
Sterilization		Non-Sterile	Non-Sterile
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)

6) Temporary Abutment

-		Subject Device	Predicate Device
Manufacturer		Izenimplant Co., Ltd.	Osstem Implant Co., Ltd.
Device Name		ZENEX Implant System	Osstem Abutment System
510(k) Number		-	K182091
Classification		Class II	Class II
Design			
Connection Type		Hex, Non-Hex	Hex, Non-Hex
Dimension	**D(Ø)**	4.0 ~ 4.5	4.0 ~ 4.5
	P/H (mm)	10	10
	Angle	0°	0°
Surface Treatment		Non-Coating	Non-Coating
Sterilization		Non-Sterile	Non-Sterile
Material		Ti 6Al 4V ELI (ASTM F136)	Pure Titanium (Gr.3)

7) Healing Abutment

-		Subject Device	Predicate Device
Manufacturer		Izenimplant Co., Ltd.	Neobiotech Co., Ltd.
Device Name		ZENEX Implant System	IS-III active System
510(k) Number		-	K181138
Classification		Class II	Class II
Design			
Connection Type		Non-Hex	Non-Hex
Dimension	**D(Ø)**	4.3 ~ 9.0	4.0 ~ 9.0
	P/H (mm)	2.0 ~ 9.0	2.3 ~ 7.8
	Angle	0°	0°
Surface Treatment		Non-Coating	Non-Coating
Sterilization		Gamma	Gamma
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)

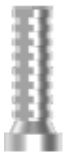
8) Cover Screw

-		Subject Device	Predicate Device
Manufacturer		Izenimplant Co., Ltd.	Neobiotech Co., Ltd.
Device Name		ZENEX Implant System	IS-III active System
510(k) Number		-	K181138
Classification		Class II	Class II
Design			
Connection Type		Non-Hex	Non-Hex
Dimension	**D(Ø)**	3.0 ~ 3.9	3.45 ~ 3.6
	Length (mm)	5 ~ 7.3	5.85 ~ 8.0
	Angle	0°	0°
Surface Treatment		No Treatment	No Treatment / Anodizing
Sterilization		Gamma	Gamma
Material		Ti 6Al 4V ELI (ASTM F136)	Ti 6Al 4V ELI (ASTM F136)

9) Multi Ti Link Cylinder

-		Subject Device	Predicate Device
Manufacturer		Izenimplant Co., Ltd.	Osstem Implant Co., Ltd.
Device Name		ZENEX Implant System	Osstem Abutment System
510(k) Number		-	K182091
Classification		Class II	Class II
Design		 (Multi Ti Link Cylinder)	 (Multi Combination Cylinder)
Connection Type		Non-Hex	Non-Hex
Dimension	**D(Ø)**	4.8	5.0
	L (mm)	4.5	7.3
	Angle	0°	0°
Surface Treatment		Non-Coating	Non-Coating
Sterilization		Non-Sterile	Non-Sterile
Material		Ti 6Al 4V ELI (ASTM F136)	Titanium Gr. 3 (ASTM F67)

10) Multi Temporary Cylinder

-		Subject Device	Predicate Device
Manufacturer		Izenimplant Co., Ltd.	Osstem Implant Co., Ltd.
Device Name		ZENEX Implant System	Osstem Abutment System
510(k) Number		-	K182091
Classification		Class II	Class II
Design		 (Multi Temporary Cylinder)	 (Esthetic-low Temporary Cylinder)
Connection Type		Non-Hex	External Hex
Dimension	**D(Ø)**	4.8	4.8, 5.5
	L (mm)	12	12
	Angle	0°	0°
Surface Treatment		Non-Coating	Non-Coating
Sterilization		Non-Sterile	Non-Sterile
Material		Ti 6Al 4V ELI (ASTM F136)	Titanium Gr. 3 (ASTM F67)

11) Multi CCM Cast Cylinder

-		Subject Device	Predicate Device
Manufacturer		Izenimplant Co., Ltd.	Osstem Implant Co., Ltd.
Device Name		ZENEX Implant System	Osstem Abutment System
510(k) Number		-	K182091
Classification		Class II	Class II
Design		 (Multi CCM Cast Cylinder)	 (Multi NP Cast Cylinder)
Connection Type		Non-Hex	Non-Hex
Dimension	**D(Ø)**	4.8	5.0
	L (mm)	11	7.3
	Angle	0°	0°
Surface Treatment		Non-Coating	Non-Coating
Sterilization		Non-Sterile	Non-Sterile
Material		CoCrMo Alloy	CoCrMo Alloy

6.2 Comparison Conclusion to predicate device

The subject devices are substantially equivalent to the predicate and reference devices with respect to indications for use, technology and construction. The differences between the predicate devices and the subject devices are minor and any risks have been mitigated through testing.

7. NON-CLINICAL DATA

As part of demonstrating substantial equivalence of the ZENEX Implant System to the predicate devices, Izenimplant Co., Ltd. conducted performance testing on the subject devices. Although there are slightly different points such as dimension or material, it does not impact the ability to determine substantial equivalence of the subject devices because the substantial equivalence of performance for ZENEX Implant System is demonstrated by the following verification and validation data to demonstrate the safety and performance effectiveness.

- Sterilization Validation

  1) Gamma Sterilization Products

  ZENEX Fixture (ZENEX MULTI Fixture and ZENEX PLUS Fixture), Healing Abutment and Cover Screw are sterilized by gamma on the sterilization process.

  A. Gamma Sterilization Validation in accordance with ISO 11137-1: 2006+A2:2018, ISO 11137-2:2013 and ISO 11137-3:2017

  2) User Moist Heat Sterilization Product

  All Abutment and accessories, excepting Healing Abutment and Cover Screw, are provided non-sterilize
  However, the device is intended to be sterilized by user moist heat sterilization.

  A. Moist Heat Sterilization Validation Report in accordance with ISO 11138-1:2017, ISO 11138-3:2017, ISO 17665-1:2006, ISO/TS 17665-2:2009, ISO 11737-1:2018 and ISO 11737-2:2019

- Packing Validation with shelf-life and integrity test

  Stability and the effectiveness of packaging as sterilized product (ZENEX Fixtures, Healing Abutment and Cover Screw) by evaluation in process of time and performance of packaging material according to the ISO 11607-1:2019, ISO 11607-2:2019, ISO 11137, ASTM F1980, ASTM F88, ASTM F1140, ASTM F1929, ASTM F1140

- Biocompatibility Test

  The biocompatibility tests were performed to protect patients from undue risks arise from biological hazards associated with materials of manufacture and final device. The tests were performed in accordance with ISO 10993-1, ISO 10993-5, and FDA Guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."

- Performance

  The following tests were performed to assess effectiveness of the product performance including mechanical properties. The tests were performed in accordance with following standards and the "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments"

  The mechanical properties tests were performed by being based on each product different properties and dimensions. Fatigue testing was conducted on worst-case constructs per ISO 14801

- Surface Treatment Test

  1) SLA Surface Treatment Product

  The surface treatment information with SLA (Sandblasted with Large-grit and Acid-etching) was provided. To analyze surface modification, SEM, EDS images including ICP and IC analysis result were provided to demonstrated removal of manufacturing, residuals (blast media and acids).

  2) TiN Coating Surface Treatment Product

  The surface treatment information with TiN Coating was provided. To analyze surface modification, surface characteristic including physical properties (thickness and abrasion) and surface roughness data were provided and it demonstrated substantial equivalence.

- MR Environment Condition

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

- Endotoxin Batch Test

  Pyrogenicity information provided is based on FDA Guidance “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile. Furthermore, the endotoxin level of the test item was determined and was within the limit of 20 EU/device. The Bacterial Endotoxin Testing (BET) was performed by the chromogenic kinetic method.
  LAL tests was performed according to the United States Pharmacopoeia (USP<85> and USP <161>) referenced FDA Guidance (Pyrogen and Endotoxins Testing: Questions and Answers; 2012-06) and the ANSI/AAMI ST72.

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

8. CLINICAL AND ANIMAL TEST

Clinical and animal testing were not performed for ZENEX Implant System as part of the premarket notification requirements for this 510(k) submission and the subject of this premarket submission, ZENEX Implant System, did not require clinical and animal studies to support substantial equivalence

9. CONCLUSION

The comparison between the subject devices and the predicate devices shows that the general information, some technical and material information are the same. Although there are some differences, the performance test reports are supported to the substantial equivalence of the subject device, the performance test reports are provided to demonstrate substantial equivalence of the subject devices. Therefore, we conclude that the different characteristics do not raise different questions of safety and effectiveness, and thus the subject devices are substantially equivalent to the predicate devices.