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

August 24, 2023

Re: K231557
Trade/Device Name: ZENEX FreeMilling & CCM Cast Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 30, 2023
Received: May 30, 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)*

Device Name
ZENEX FreeMilling & CCM Cast Abutment

Indications for Use *(Describe)*
The ZENEX FreeMilling & CCM Cast Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

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 FreeMilling & CCM Cast Abutment
- Common Name: Dental Implant Abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date Prepared: 08/24/2023

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

Primary Predicate

- K161689, OSSTEM Implant System – Abutment by Osstem Implant Co., Ltd.

Reference devices

- K192263, UCLA CCM Abutment by DIO Corporation
- K211090, ZENEX Implant System by Izenimplant Co., Ltd.

Indication for Use:
The ZENEX FreeMilling & CCM Cast Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

Device Description:

ZENEX FreeMilling & CCM Cast Abutment consists of FreeMilling Abutment and CCM Cast Abutment.
ZENEX FreeMilling & CCM Cast Abutment is compatible with the fixtures below:

K number	Device Name	Dimension Ranges
K211090	ZENEX Implant System (ZENEX MULTI&PLUS Fixture)	Ø 3.75 x 8.5, 10, 11.5, 13, 15 Ø 4.25 x 7, 8.5, 10, 11.5, 13, 15 Ø 4.6 x 7, 8.5, 10, 11.5, 13, 15 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

Tolerance of dimension shall be within ± 1% range.

The dimensions of abutments are as following:

Device Name	Dimension Ranges	Gingival Heights (mm)	Minimum Post height (mm)	Angulation
FreeMilling Abutment	Ø 4.0/4.5/5.0/5.2/5.7/ 6.0/6.5/7.0	1.3/1.8/2.8/3.8	4	0°
CCM Cast Abutment	Ø 4.0 / 4.5	0.8 / 2.8	4	0°

The Abutments have below featured:

Name	Uses	Surface	Connection
FreeMilling Abutment	The Abutment is connected with fixture, and it supports prosthesis which restores tooth function.	Partial TiN coated in upper	Screw retained
CCM Cast Abutment	It is an abutment that is used when making a retained / customized prosthesis.	NA	Screw retained

Tolerance of dimensions for Abutments shall be within ± 1% range.

ZENEX FreeMilling & CCM Cast Abutment is provided non-sterile.

Materials:

- FreeMilling Abutment is fabricated of Ti-6Al-4V ELI according to ASTM F136-13
- CCM Cast Abutment is fabricated of Co-Cr-Mo according to ASTM F1537-11

Summaries of Technological Characteristics & Substantial Equivalence Discussion

FreeMilling Abutment

		Subject Device		Primary Predicate	
Manufacturer		Izenimplant Co.,Ltd		OSSTEM Implant Co., Ltd.	
Product Name		ZENEX FreeMilling & CCM Cast Abutment		OSSTEM Implant System - Abutment	
Model Name		FreeMilling Abutment		FreeForm ST Abutment	
510(K) Number		K231557		K161689	
Indications for Use		The ZENEX FreeMilling & CCM Cast Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.		The OSSTEM Implant System – Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdenture	
Design					
		Hex	Non-Hex	Hex	Non-Hex
Hand Milling Only		Yes		Yes	
Dimension	D	4.0/4.5/5.0/5.2/5.7/6.0/6.5/7.0		Φ4.0/5.0/5.5/6.0/7.0	
	G/H	1.3/1.8/2.8/3.8		1.5 / 3.5	
	P/H	8 / 9mm		9/10.5mm	
	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 Sterilziation		End User Sterilziation	
SE Discussion		The Subject Device and Primary Predicate (K161689) have same indications for use, diameters, material, and sterilization method. The differences between two devices are gingival height and post height, however, the values are very similar and these differences are not important factor for the device performance. Both devices are substantial equivalent.			

CCM Cast Abutment

		Subject Device		Reference Device	
Manufacturer		Izenimplant Co.,Ltd		DIO Corporation	
Product Name		ZENEX FreeMilling & CCM Cast Abutment		UCLA CCM Abutment	
Model Name		CCM Cast Abutment		UCLA CCM Abutment	
510(K) Number		K231557		K192263	
Design					
		Hex	Non-Hex	Hex	Non-Hex
Dimension	D	4.0 / 4.5		4.0/4.5	
	G/H	0.8 / 2.8		1.0/3.0	
	P/H	10.0		10.0	
	Angle	0°		0°	
Material		CCM Abutment	CoCrMo Alloy	CCM Abutment	CoCrMo Alloys
		Plastic Sleeve	POM	Plastic Sleeve	POM
Surface		Non-Coating		Non-Coating	
Sterilization		Steam Sterilization by user (Delivered non sterile)		Steam Sterilization by user (Delivered non sterile)	

SE Discussion	The Subject Device and Reference Device (K192263) have same indications for use, diameters, material, and sterilization method. The differences between two devices are gingival height and post height, however, the values are very similar, and these differences are not important factor for the device performance. Both devices are substantial equivalent.

Non-Clinical Test Data

Below tests were performed on subject device:

- Biocompatibility Testing on subject CCM Cast Abutment according to ISO 10993-1:2020
- 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

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

- 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
- Biocompatibility testing for Abutments made with Ti-6Al-4V ELI according to ISO 10993-1:2009 referenced in K211090

The surface modification information of TiN Coating such as chemical composition, coating thickness, abrasion characteristics, and SEM imaging provided in the previous cleared device, K211090 can be leveraged for the subject FreeMilling abutment.

The end user sterilization test was performed for predicate device, K211090 and leveraged for the subject device made with Ti-6Al-4V ELI because the product material, manufacturing process, sterilization methods and packaging of both products are exactly same.
The end user sterilization validation is performed on the subject CCM Cast Abutment according to ISO 17665-1 and ISO 17665-2. The worst-case construct was tested, and results demonstrated equivalence to the predicate device.

The Biocompatibility Test was conducted on the predicate device, K211090 and leveraged for the subject device made with Ti-6Al-4V ELI because both products are manufactured with same materials and manufacturing process. It demonstrates that the subject device is biocompatible and substantial equivalence with the predicate.
Biocompatibility Testing was performed according to ISO 10993-1:2009, "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,*" and to the FDA Guidance document, "*Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff"*, Document issued on: June 16, 2016", for subject CCM Cast Abutments

MR Environment Condition
Non-clinical worst-case MRI review was performed to evaluate the metallic. Dentis I-FIX Abutment in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry 0., 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 bodied, 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 non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion

ZENEX FreeMilling & CCM Cast Abutment 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 FreeMilling & CCM Cast Abutment and its predicates are substantially equivalent.