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

January 12, 2023

Re: K222976
Trade/Device Name: MU System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 14, 2022
Received: October 14, 2022

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
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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)*
K222976

Device Name
MU System

Indications for Use *(Describe)*
MU System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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Device Information

- Trade Name: MU System
- Common Name: Endosseous Dental Implant Abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date prepared: 1/12/2023

Predicate Devices:
Primary Predicate
K211090, ZENEX Implant System by Izenimplant Co., Ltd

Reference Device
K210134, Dentis s-Clean s-Line by Dentis Co., Ltd

Indication for Use:
MU System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of 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.

Device Description:
MU Ti Cylinder is manufactured by titanium alloy conforming to ASTM F136 and is used with s-Clean MU Angled Abutment and s-Clean MU Straight Abutment to provide support for multiple unit prosthetic restoration such as bridges, or overdentures. The subject abutments are indicated for cemented or "Screw-and Cement-Retained Prosthesis(SCRP)" restorations and supplied non-sterile.
s-Clean MU Healing Cap is manufactured by titanium alloy conforming to ASTM F136 and used with our cleared device, K210134 such as s-Clean MU Angled Abutment and s-Clean MU Straight Abutment and used for protecting inner hole of fixture and adjusting the appropriate height during the healing period.

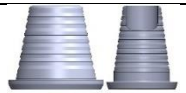
Materials:

- MU Ti Cylinder and s-Clean MU Healing Cap are fabricated from Ti-6Al-4V ELI (Conforming to ASTM Standard F136).

Summaries of Technology Characteristics

The subject device is substantially equivalent to the current cleared devices. They are substantially equivalent in intended use, material and connection interfaces to the implants are similar for each individual diameter and connection type. Comparison demonstrating Substantial Equivalence follows:

<MU Ti Cylinder>

	Subject Device	**Primary Predicate**
Applicant	Dentis Co., Ltd	Izenimplant Co., Ltd
Trade Name	MU System	ZENEX Implant System
510(k) No.	N/A	K211090
Classification Name	Endossoeus Dental Implant Abutment	Endossoeus Dental Implant Abutment
Product Code	NHA	NHA
Class	Class II	Class II
Design		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Diameter (mm)	5.1	4.8
Length	4.5 and 5.9	4.5
Sterile	End user sterilization	End user sterilization
Indications For Use	MU System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	ZENEX Implant System 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.
Substantial Equivalence Comparison	The subject MU Ti Cylinder is substantially equivalent in designs, material, diameter, sterile method, indications and principle of operation with the identified primary predicate device(K211090). MU Ti Cylinder is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured, and tested in compliance with FDA's Class II special controls guidance document root-food endosseous dental implants and endosseous dental implant abutments. The difference between the subject and primary predicate is indications. The indications of subject and primary predicate device are identical except the indications for wide fixture system. Since the indications of subject device are in range of the primary predicate, this different doesn't impact the safety and effectiveness. Therefore, subject device is substantially equivalent.	

<s-Clean MU Healing Cap >

	Subject Device	**Reference Device**
Applicant	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	MU System	Dentis s-Clean s-Line
510(k) No.	N/A	K210134
Classification Name	Endossoeus Dental Implant Abutment	Endossoeus Dental Implant Abutment
Product Code	NHA	NHA
Class	Class II	Class II
Design		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Diameter (mm)	5.8 and 6.8	4.8
Length	4.1	4.1
Sterile	End User Sterilization	End User Sterilization
Substantial Equivalence Comparison	The subject s-Clean MU Healing Cap is substantially equivalent in designs, length, material, sterile method and indication with the identified device (K210134). S-Clean MU Healing Cap is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-food endosseous dental implants and endosseous dental implant abutments. The diameter of subject device is larger than the predicate and it doesn't impact the fundamental technology. Therefore, the subject device is substantially equivalent.	

Non-Clinical Testing

Below tests are leveraged for the subject device:

- End User Steam Test on s-Clean MOA Abutment for subject device referenced in K111364 according to ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79:2010
- Fatigue Test under the worst-case scenario according to ISO 14801:2016 referenced in K210134

Non-clinical testing was conducted in accordance with FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".

Fatigue testing was not performed for subject device because the subject device does not present a new worst-case scenario, therefore, the fatigue testing is leveraged from the identified predicate, K210134.

For all devices delivered non-sterile to be end-user sterilized, the recommended sterilization has been validated according to ISO 17665-1 and ISO 17665-2 and to applicable recommendations in the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015".

Biocompatibility tests on representative test articles for subject MU Ti cylinder and s-Clean MU Healing Cap according to ISO 10993-1:2009, ISO 10993-5:2009, ISO-10:2010, and ISO 10993-11:2017.

Non-clinical worst-case MRI review was performed to evaluate the MU 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 4 9.2 (2 01 9): 7 8 3-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, a n d 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 MU System 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 device. Therefore, MU System and its predicates are substantially equivalent.