



January 12, 2024

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

Re: K232170
Trade/Device Name: Ti Link Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 14, 2023
Received: December 14, 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 (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.

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

Indications for Use

Submission Number (if known)

K232170

Device Name

Ti Link Abutment

Indications for Use (Describe)

Ti Link Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

All digitally designed abutments for use with Ti Link Abutment are intended to be manufactured at a Izenimplant validated milling center.

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)

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510(k) Summary

Submitter

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Device Information

- Trade Name: Ti Link Abutment
- Common Name: Endosseous dental implant abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3630
- Device Class: Class II
- Date prepared: 01/11/2024

Predicate Devices:

The subject device is substantially equivalent to the following predicate device:

Primary Predicate

- K181037, DIO CAD/CAM Abutment by DIO Corporation

Reference Predicate

- K211090, ZENEX Implant System by Izenimplant Co., Ltd.
- K091096, NATURAZ SERIES, MODEL B16, B20, B42, B60, B98, B100 by DENTAL SOLUTIONS, INC.
- K110508, 3M RelyX Ultimate Cement by 3M ESPE

Device Description

The Ti Link Abutment is a two-piece abutment intended to provide support for restorations such as crowns and bridges. The two pieces which compose the final abutment consist of the pre-manufactured titanium base component composed of titanium alloy conforming to ASTM F136, and the CAD/CAM patient matched mesostructure composed of zirconia (K091096). The diameters of the pre-manufactured titanium base component are 4.0/4.5mm. The final two-piece abutment is fixed to the implant with an abutment screw composed of titanium alloy conforming to ASTM F136.

Ti Link Abutment is provided non-sterile, therefore must be sterilized after the cementation of the CAD/CAM patient matched mesostructure on the pre-manufactured titanium base component.

The abutments are compatible with the implants cleared under K211090.

Proprietary Name	ZENEX Multi Fixture	ZENEX Plus Fixture
Compatible Implants (K number)	K211090	
Implant diameter size	Ø 3.75, 4.25, 4.6, 5.05, 5.4, 5.9, 6.75	
Implant Interface Connection Type/Size(mm)	I-System: Internal connection type/3.2 (Mini), 3.35 (Regular/Wide) T-System: Internal connection type/2.8 (Mini), 3.35 (Regular/Wide)	
Type of Implant-Abutment Connection	Hex/Non-Hex	

Raw material blanks

- K091096, NATURAZ SERIES, MODEL B16, B20, B42, B60, B98, B100 by DENTAL SOLUTIONS, INC.

Raw material cement

- K110508, 3M RelyX Ultimate Cement by 3M ESPE

The CAD/CAM patient matched mesostructure that is added to the pre-manufactured titanium base component to create the final abutment design should be designed and milled through the CAD/CAM software, according to the prosthetic planning and patient clinical situation. The coping and crowns designed using these or more recent versions of the CAD/CAM System, within the design limits as defined within the design software, are compatible with the Ti Link Abutment.

The coping would be manufactured by Izenimplant only with design input using CAD/CAM Software from and by Izenimplant milling center.

CAD/CAM patient matched mesostructure is made from NaturaZ (K091096) and is cemented to the pre-manufactured titanium base component using RelyX cement (K110508) to complete the final finished abutment.

Design Limitation for CAD/CAM patient matched mesostructure:

Design Parameter	Design Limit
Minimum and Maximum angulation (°)	0-15
Minimum and Maximum cuff height (mm)	0-5.0
Minimum thickness (mm)	0.55
Minimum and Maximum length of abutment post (length above the abutment collar / gingival height) (mm)	4.0-4.5

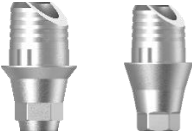

Indication for Use

Ti Link Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

All digitally designed abutments for use with Ti Link Abutment are intended to be manufactured at a Izenimplant validated milling center.

Summaries of Technological Characteristics

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

	Subject Device	Primary Predicate Device			
Applicant	Izenimplant Co., Ltd.	DIO Corporation			
Trade Name	Ti Link Abutment	DIO CAD/CAM Abutment			
510(K) No.	NA	K181037			
Classification Name	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant, Abutment (872.3630)			
Product Code	NHA	NHA			
Class	II	II			
Material	- Ti-6Al-4V ELI (ASTM F136): Pre-manufactured titanium base component - Zirconia Oxide: CAD/CAM patient matched mesostructure component	Ti-6Al-4V ELI (ASTM F136) Zirconia Oxide			
Titanium base component representative image					
Diameters (mm)	4.0/4.5	4.0/4.5/5.5			
Mesostructure Angulation (°)	0-15	0-15			
Mesostructure material	Zirconia (K091096)	Zirconia			
Sterile	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)			
Type of Retention	Screw-retained to the implant. The prosthesis can be cement retained to the abutment.	Screw-retained to the implant. The prosthesis can be cement retained to the abutment.			
Coating	Non-Coating	Non-Coating			
Indications For Use	Ti Link Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. All digitally designed abutments for use with Ti Link Abutment are intended to be	DIO CAD/CAM Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. <table border="1" data-bbox="878 1843 1453 1927"> <tr> <td>Implant System Compatibility</td> <td>Implant Diameter (mm)</td> <td>Platform Diameter (mm)</td> </tr> </table>	Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)
Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)			

	<p>manufactured at a Izenimplant validated milling center.</p>	<p>UF(II) Narrow Implant System</p>	<p>3.0/ 3.3</p>	<p>3.0/ 3.3</p>
		<p>UF Sub merged Implant System</p>	<p>3.8/4.0/4.5/ 5.0/5.5/6.0/ 6.5/7.0</p>	<p>3.8/4.0/4.5/ 5.0/5.5/6.0/ 6.5/7.0</p>
		<p>UF(II) Implant System</p>	<p>3.8/4.0/4.5/ 5.0/5.5</p>	<p>3.8/4.0/4.5/ 5.0/5.5</p>
		<p>Patient specific abutment is intended for use with the UF(II) Implant System. All digitally designed abutments for use with DIO CAD/CAM Abutments are intended to be manufactured at a DIO Corporation validated milling center.</p>		
<p>Substantial Equivalence Comparison</p>	<p>The subject Ti Link Abutment is substantially equivalent in designs, dimensions, material, indications, and technological characteristics with the identified primary predicate device. The Ti Link Abutment 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.</p> <p>The diameters of the subject device are slightly different from the predicate devices. However, the subject diameters are in the range of diameters of predicates and this dimensional difference doesn’t affect device safety and effectiveness.</p> <p>The Indications for Use of the subject and primary predicate device are identical other than the compatible implant bodies. This difference is mitigated by fatigue testing and identification of reference device for compatible implant bodies. Both the predicate and subject devices are intended to be milled into patient specific abutments using CAD/CAM technology under the manufacturing control of the sponsor.</p> <p>Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate and do not raise different questions of safety and effectiveness than the predicate.</p>			

Non-clinical Testing

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Fatigue Test according to ISO 14801:2016 under worst case scenario (two occurrences)
- End User Steam Sterilization Tests according to ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79:2010
- Cytotoxicity testing according to ISO 10993-5:2009

Below tests were performed for predicate devices, K211090 and leveraged for the subject device:

- Biocompatibility tests according to ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

Biocompatibility test data was used to evaluate the proposed device's substantial equivalence compared to the predicate device which is owned by the applicant. The results of the above tests have met the criteria of the standard and demonstrated the substantial equivalence with the predicate device.

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", and it consisted of testing finished assembled implant/abutment systems of the worst-case scenario through fatigue testing.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the Ti Link Abutment 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 Ti Link 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 device. Therefore, Ti Link Abutment and its predicates are substantially equivalent.