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

January 13, 2023

Re: K222913
Trade/Device Name: s-Clean Link Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 9, 2022
Received: December 9, 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
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)*

K222913

Device Name

s-Clean Link Abutment

Indications for Use *(Describe)*

s-Clean 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.

No.	Subject Device	Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)	K number
1	s-Clean Link Abutment Regular	Dentis s-Clean s-Line	Ø5.8, 6.8 and 7.8	Ø4.3, 4.5	K210134
2	s-Clean Link Abutment Mini	Dentis s-Clean s-Line Mini	Ø5.8, 6.8 and 7.8	Ø4.3, 4.5	K210080

s-Clean Link Abutment is intended for use with the Dentis s-Clean s-Line and Dentis s-Clean s-Line Mini according to connector part in the chart. All digitally designed zirconia for use with s-Clean Link Abutment are intended to be manufactured at a Dentis 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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April Lee
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Irvine, CA 92620 USA
Email: withus6664@gmail.com
Phone: 1-909-274-9971
Fax: 1-909-460-8122

Device Information

- Trade Name: s-Clean 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: 01/12/2023

Predicate Devices:

Primary Predicate
- K181037, DIO CAD/CAM Abutment by DIO CORPORATION

Reference Device
- K210080, Dentis s-Clean s-Line Mini by Dentis Co., Ltd
- K210134, Dentis s-Clean s-Line by Dentis Co., Ltd
- K141724, UPCERA DENTAL ZIRCONIA BLANK & DENTAL ZIRCONIA PRE-SHADED BLANK by LIAONING UPCERA Co., Ltd.
- K191122, 3M RelyX Pediatric Resin Modified Glass Ionomer Cement by 3M ESPE Dental Products

Indication for Use:

s-Clean 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.

No.	Subject Device	Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)	K number
1	s-Clean Link Abutment Regular	Dentis s-Clean s-Line	Ø5.8, 6.8 and 7.8	Ø4.3, 4.5	K210134
2	s-Clean Link Abutment Mini	Dentis s-Clean s-Line Mini	Ø5.8, 6.8 and 7.8	Ø4.3, 4.5	K210080

s-Clean Link Abutment is intended for use with the Dentis s-Clean s-Line and Dentis s-Clean s-Line Mini according to connector part in the chart. All digitally designed zirconia for use with s-Clean Link Abutment are intended to be manufactured at a Dentis validated milling center.

Device Description:

The s-Clean Link Abutment is intended to provide support for customized prosthetic restorations such as crowns and bridges. The s-Clean Link Abutment is composed of two-piece abutment that is a link abutment at the bottom, a coping (CAD/CAM patient specific superstructure) at the top and screw. The bottom link abutment portion of the s-Clean Link Abutment is pre-manufactured (stock) made from a titanium alloy conforming to ASTM F136. The Top half of the s-Clean Link Abutment is composed of zirconia conforming to ISO 6872 reference to prior cleared ceramic, K141724.

s-Clean Abutment Screw s-Line is made of Ti-6Al-4V ELI (ASTM F136)

The diameters of s-Clean Link Abutment are 4.5 and 4.8mm.

s-Clean Link Abutment is provided non-sterile therefore must be sterilized after the cementation of the patient-specific superstructure on the Link Abutment.

The proposed devices are compatible with the following device.

Dental Implants

Subject Abutment	s-Clean Link Abutment Regular	s-Clean Link Abutment Mini
Compatible Implants (Knumber)	Dentis s-Clean s-Line (K210134)	Dentis s-Clean s-Line Mini (K210080)
Implant diameter size	Ø5.8, 6.8 and 7.8	Ø5.8, 6.8 and 7.8
Platform diameter size	Ø4.3, 4.5	Ø4.3, 4.5
Implant Interface Connection Type/Size(mm)	Internal connection type / 2.5Hex	Internal connection type / 2.1Hex
Type of Implant-Abutment Connection	Hex/Non Hex	Hex/Non Hex

Raw material blanks

- K141724, Upcera Dental Zirconia Blank & Dental Zircornia Pre-Shaded Blank by Liaoning Upcera Co., Ltd.

Raw material cement

- K191122, 3M RelyX Pediatric Resin Modified Glass Ionomer Cement by 3M ESPE Dental Product

The coping that composes the final abutment 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 link abutment.

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

Design Limitation for Superstructure:

	Zirconia for s-Clean Link Abutment Regular	Zirconia for s-Clean Link Abutment Mini
Minimum wall thickness	0.5	0.5
Minimum/Maximum Post Height for single-unit restorations	4.45	4.45
Maximum gingival height in the zirconia superstructure	0	0
Minimum gingival height in the Link Abutment	1	1
Maximum angulation	0	0

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 identical for each individual diameter and connection type. Comparison demonstrating Substantial Equivalence follows:

<s-Clean Link Abutment Regular>

	Subject Device	**Primary Predicate**
Applicant	Dentis Co., Ltd	DIO CORPORATION
Trade Name	s-Clean Link Abutment	DIO CAD/CAM Abutment
510(k) No.	N/A	K181037
Classification Name	Endossoeus Dental Implant Abutment	Endossoeus Dental Implant Abutment
Product Code	NHA	NHA
Class	Class II	Class II
Design		
Base Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Diameter (mm)	4.5 and 4.8	4.0, 4.5 and 5.5
Superstructure Angulation	0 ˚	0~15˚
Superstructure material	Zirconia	Zirconia
Sterile	End-User Sterile	End-User Sterile
Type of Retention	Fixture-Link Abutment : Screw Link Abutment-Zirconia Coping : Cement	Fixture-Link Abutment : Screw Link Abutment-Zirconia Coping : Cement
Zirconia Superstructure Design Parameters		
Minimum Diameter (mm)	4.5	4.0
Minimum Post Wall Thickness (mm)	0.5	0.5
Maximum Gingival Height in the Zirconia superstructure	0	0
Angulation (º)	0	0-15º

<table>
<tr>
<td>Indications For Use/ Intended Use</td>
<td>
s-Clean 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.
<table>
<tr><th>No.</th><th>Subject Device</th><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th><th>K number</th></tr>
<tr><td>1</td><td>s-Clean Link Abutment Regular</td><td>Dentis s-Clean s-Line</td><td>Ø5.8, 6.8 and 7.8</td><td>Ø4.3, 4.5</td><td>K210134</td></tr>
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Patient specific abutment is intended for use with the UF Implant System provided in the chart. All digitally designed abutment for use with DIO CAD/CAM Abutments are intended to be manufactured at a DIO Corporation validated milling center.
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<td>Substantial Equivalence Comparison</td>
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The subject s-Clean Link Abutment is substantially equivalent in designs, dimensions, material, indication, superstructure and sterile method with the identified primary predicate device. The s-Clean 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.

The diameters of the subject device are slightly different from the predicate device. However, the subject diameters are in the range of diameters of predicates and this dimensional difference doesn’t affect device safety and effectiveness.
The Indications for Use of the subject and primary predicate device are identical other than the 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. 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.
</td>
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<s-Clean Link Abutment Mini>

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<tr><td>Applicant</td><td>Dentis Co., Ltd</td><td>DIO CORPORATION</td></tr>
<tr><td>Trade Name</td><td>s-Clean Link Abutment</td><td>DIO CAD/CAM Abutment</td></tr>
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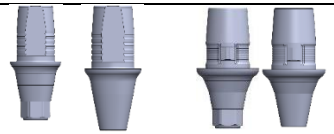
<tr><td>Design</td><td>  </td><td>  </td></tr>
<tr><td>Base Material</td><td>Ti-6Al-4V ELI (ASTM F136)</td><td>Ti-6Al-4V ELI (ASTM F136)</td></tr>
<tr><td>Diameter (mm)</td><td>4.0, 4.5 and 4.8</td><td>4.0, 4.5 and 5.5</td></tr>
<tr><td>Superstructure Angulation</td><td>0 ˚</td><td>0~15˚</td></tr>
<tr><td>Superstructure material</td><td>Zirconia</td><td>Zirconia</td></tr>
<tr><td>Sterile</td><td>End-User Sterile</td><td>End-User Sterile</td></tr>
<tr><td>Type of Retention</td><td>Fixture-Link Abutment : Screw
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<tr><td colspan="3">Zirconia Superstructure Design Parameters</td></tr>
<tr><td>Minimum Diameter (mm)</td><td>4.0</td><td>4.0</td></tr>
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Non-Clinical Testing

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

- End User Steam Sterilization Tests on s-Clean Link abutment cemented to zirconia top according to ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79:2010
- Biocompatibility tests on s-Clean Link abutment according to ISO 10993-1:2009, ISO 10993-5:2009
- Cytotoxicity testing on s-Clean Link Abutment cemented to zirconia superstructure according to ISO 10993-5:2009

Biocompatibility test was performed on subject Link abutment and subject link abutment cemented to the zirconia top. The results of the above tests have met the criteria of the standard and demonstrated 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".

For all subject 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". The worst-case construct was tested, and the result report is attached.

MR Environment Condition
Non-clinical worst-case MRI review was performed to evaluate the metallic s-Clean Link Abutment 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.

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

Conclusion
The s-Clean 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, s-Clean Link Abutment and its predicates are substantially equivalent