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

May 24, 2023

Re: K230523
Trade/Device Name: s-Clean Link Abutment Narrow
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 25, 2023
Received: February 27, 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)*
K230523

Device Name
s-Clean Link Abutment Narrow

Indications for Use *(Describe)*
s-Clean Link Abutment Narrow is intended for use with dental implant as a support for single or multiple tooth prostheses in mandibular central and lateral incisors and maxillary lateral incisors.

No.	Subject Device	Implant System Compatibility	Implant Diameter (Ø)	Platform Diameter (Ø)	K number
1	s-Clean Link Abutment Narrow	s-Clean OneQ-SL Narrow Implant System	3.3	3.3	K161244

s-Clean Link Abutment Narrow is intended for use with the s-Clean OneQ-SL Narrow Fixture according to connector part in the chart. All digitally designed zirconia for use with s-Clean Link Abutment Narrow 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.

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: s-Clean Link Abutment Narrow
- 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: 05/23/2023

Predicate Devices:

Primary Predicate
- K222913, s-Clean Link Abutment by Dentis Co., Ltd.

Reference Device
- K161244, s-Clean OneQ-SL Narrow Implant System by Dentis Co.,Ltd

Indications for Use:

s-Clean Link Abutment Narrow is intended for use with dental implant as a support for single or multiple tooth prostheses in mandibular central and lateral incisors and maxillary lateral incisors.

No.	Subject Device	Implant System Compatibility	Implant Diameter (Ø)	Platform Diameter (Ø)	K number
1	s-Clean Link Abutment Narrow	s-Clean OneQ-SL Narrow Implant System	3.3	3.3	K161244

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

Device Description:
The s-Clean Link Abutment Narrow is intended to provide support for customized prosthetic restorations such as crowns and bridges. The s-Clean Link Abutment is composed of a two-piece abutment that is a link abutment at the bottom and a coping (CAD/CAM patient specific superstructure) as the top-half. The submission also includes an abutment fixation screw. The s-Clean Link Abutment are pre-manufactured (stock) abutments, made from a titanium alloy conforming to ASTM F136.

The top half of the s-Clean link abutment composed of zirconia is referenced from our previously cleared K222913 submission.
s-Clean Abutment Screw is made of Ti-6Al-4V ELI (ASTM F136) and cleared in K161244.
The diameters of s-Clean Link Abutment Narrow are 4.0 and 4.5mm.
s-Clean Link Abutment Narrow is provided non-sterile and must be sterilized after the cementation of the patient-specific superstructure on the Link Abutment Narrow.

The proposed devices are compatible with the following device:

Dental Implants

Subject Abutment	s-Clean Link Abutment Narrow
Compatible Implants (Knumber)	s-Clean OneQ-SL Narrow Fixture (K161244)
Implant diameter size	Ø3.3
Implant Length	10, 12 and 14mm
Implant Interface Connection Type	Internal connection type / Screw retained
Type of Implant-Abutment Connection	Hex/Non Hex

Raw material cement

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

The ceramic and cement used for the subject device is identical to the primary predicate.
The coping that composes the final abutment should be designed and milled through the CAD/CAM software, at a Dentist validated milling center, according to the prosthetic planning and patient clinical situation. The coping would be manufactured by Dentis only with design input using CAD/CAM Software from and by Dentis milling center.

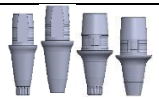
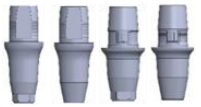
Design Limitation for Superstructure:

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

	Subject Device	**Primary Predicate**
Applicant	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	s-Clean Link Abutment Narrow	s-Clean Link Abutment
510(k) No.	K230523	K222913
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)	4.0 and 4.5	4.5 and 4.8
Superstructure Angulation	0 ˚	0 ˚
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
MRI Safety	Same MR conditional labeling	Same MR conditional labeling
Zirconia Superstructure Design Parameters		
Minimum Diameter (mm)	4.0	4.5
Minimum Post Wall Thickness (mm)	0.5	0.5
Maximum Gingival Height in the Zirconia superstructure	0	0
Angulation (º)	0	0

<table>
<tr>
<td>Indications For Use/ Intended Use</td>
<td>
s-Clean Link Abutment Narrow is intended for use with dental implant as a support for single or multiple tooth prostheses in mandibular central and lateral incisors and maxillary lateral incisors.
<table>
<tr><th>No.</th><th>Subject Device</th><th>Implant System Compatibility</th><th>Implant Diameter</th><th>Platform Diameter</th><th>K number</th></tr>
<tr><td>1</td><td>s-Clean Link Abutment Narrow</td><td>s-Clean OneQ-SL Narrow Fixture</td><td>Ø3.3</td><td>Ø3.3</td><td>K161244</td></tr>
</table>
s-Clean Link Abutment Narrow is intended for use with the s-Clean OneQ-SL Narrow Fixture according to connector part in the chart. All digitally designed zirconia for use with s-Clean Link Abutment Narrow are intended to be manufactured at a Dentis validated milling center.
</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>
<tr><td>2</td><td>s-Clean Link Abutment Mini</td><td>Dentis s-Clean s-Line Mini</td><td>Ø5.8, 6.8 and 7.8</td><td>Ø4.3, 4.5</td><td>K210080</td></tr>
</table>
s-Clean Link Abutment is intended for use with the Dentis s-Clean s-Line and Dentis s-Clean s-Line Mini provided in the chart. All digitally designed abutment for use with Dentis CAD/CAM Abutments are intended to be manufactured at a Dentis validated milling center.
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<tr>
<td>Substantial Equivalence Comparison</td>
<td colspan="2">
The subject s-Clean Link Abutment Narrow is substantially equivalent in designs, dimensions, material, superstructure and sterile method with the identified primary predicate device, K222913. The s-Clean Link Abutment Narrow 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, 4.0mm of the subject device is different from the predicate device, however, this is due to the difference in dimension of the implant body.
The Indication for Use of the subject device and predicate device is also different. While the predicate device is used to support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient, the implant diameter 3.3mm for the subject device is used to support for single or multiple tooth prostheses mandibular central and lateral incisors and maxillary lateral incisors.

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>
</tr>
</table>

Non-Clinical Testing

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

- End User Sterilization Validation test for s-Clean Link abutment cemented to zirconia top according to ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79:2010 referenced in K222193
- Biocompatibility tests on s-Clean Link abutment according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010 and ISO 10993-11:2017 referenced in K222913
- Cytotoxicity testing on s-Clean Link Abutment cemented to zirconia superstructure according to ISO 10993-5:2009 referenced in K222193

The end user sterilization test was performed for predicate device, K222193 and leveraged for the subject device because the product category, material, manufacturing process, facility, and packaging of the both products are exactly same.

The Biocompatibility Test was conducted on the predicate device, K222193 and leveraged for the subject device 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.

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".

MR Environment Condition
Non-clinical worst-case MRI review was performed to evaluate the metallic s-Clean Link Abutment Narrow 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. The subject device and primary predicate device have the same MR conditional labeling.

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

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