June 16, 2022

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

Re: K220440
Trade/Device Name: Dentis s-Clean Abutment Mini
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 14, 2022
Received: May 17, 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
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)*
K220440

Device Name
Dentis s-Clean Abutment Mini

Indications for Use *(Describe)*
The Dentis s-Clean Abutment Mini is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal 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.

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510(k) Summary

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Device Information

- Trade Name: Dentis s-Clean Abutment Mini
- Common Name: Endosseous dental implant abutment
- Classification Name: Endosseous dental implant abutment
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date prepared: 06/15/2022

Predicate Devices:
Primary Predicate
K171027, Dentis Dental Implant System by Dentis Co., Ltd

Reference Device
K161244, s-Clean OneQ-SL Narrow Implant System by Dentis Co., Ltd.
K210080, Dentis s-Clean s-Line Mini by Dentis Co., Ltd.

Indication for Use:
The Dentis s-Clean Abutment Mini is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

Device Description:
Dentis s-Clean Abutment Mini is composed of Abutments. The abutments are made of Ti-6Al-4V ELI according to ASTM F136 and Cobalt-28Chromium-6Molybdenum Alloy ASTM F1537.
The s-Clean O-Ring Abutment s-Line and s-Clean TiN Half Coating Sub-Octa Abutment is screw assembled design but s-Clean CCM UCLA Abutment s-Line is screw separation design.

The s-Clean TiN Half Coating Sub-Octa Abutment is always to be combined with a casting abutment (e.g., Gold Cylinder) or burn-out plastic sleeve for single-unit loading. The minimum post height of s-

Clean TiN Half Coating Sub-Octa Abutment when combined with casting abutment (e.g., Gold Cylinder) or burn-out plastic sleeve for single-unit loading is 4mm.
The minimum post height of s-Clean CCM UCLA Abutment s-Line for single-unit loading is 4mm.

The Subject device is compatible with implants cleared in K210080.
Compatible fixture diameters are Ø5.8, 6.8 and Ø7.8 and lengths are 7.5, 9.5, 11.4 and 11.5mm.

Compatible fixture, K210080, has dual screw-joint (structured with Upper and Lower screw joint) and a hex anti-rotation design connection. As explained in K210080, there are two-screw-joint features, 1.6M screw (Lower part) or 2.0M Screw (Upper Part) for diverse screw connection with other abutments. s-Clean O-Ring Abutment s-Line and s-Clean TiN Half Coating Sub-Octa Abutment have Upper M2.0 Screw and s-Clean CCM UCLA Abutment s-Line has Lower M1.6 screw. When dividing screw assemble design, screw assembled one-piece abutment is connected with upper screw and screw separated two-piece abutment is connected with lower screw.

The dimensions of abutments are as following:

No.	**Device Name**	**Diameter X Total Length**	**Angulation**
1	s-Clean O-Ring Abutment s-Line	Ø4.5 X 10.71 and 12.71mm	0º
2	s-Clean TiN Half Coating Sub-Octa Abutment	Ø4.8 X 8.16, 8.66, 9.66, 10.66, 11.66 and 12.66mm	0º
3	s-Clean CCM UCLA Abutment s-Line	Ø4.0 X 1, 3mm (Gingival Height)	0º

The Abutments have below featured:

Name	Uses	Surface	Connection
s-Clean O-Ring Abutment s-Line	It is used to retain an overdenture prosthetics.	N/A	Screw retain
s-Clean TiN Half Coating Sub-Octa Abutment	This Abutment is connected with fixture and it supports prosthesis which restore tooth function.	TiN Coating	Screw retain
s-Clean CCM UCLA Abutment s-Line	This Abutment is connected with fixture and it supports prosthesis which restore tooth function.	N/A	Screw retain

Materials:

- s-Clean O-Ring Abutment s-Line and s-Clean TiN Half Coating Sub-Octa Abutment is fabricated from Ti-6Al-4V ELI (Conforming to ASTM Standard F136).
- S-Clean CCM UCLA Abutment s-Line is fabricated from Cobalt-28Chromium-6Molybdenum Alloy (Conforming to ASTM F1537)
- CCM UCLA s-Line Abutment Screw is 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 product spec as diameter and length. Comparison demonstrating Substantial Equivalence follows:

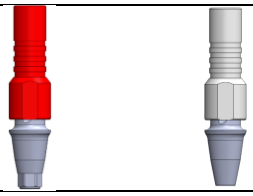
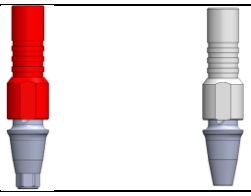
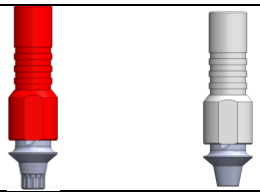
1. s-Clean O-Ring Abutment s-Line

	Subject Device	**Primary Predicate**
Applicant	Dentis Co., Ltd.	Dentis Co., Ltd.
Trade Name	Dentis s-Clean Abutment Mini	Dentis Dental Implant System
510(k) No.	-	K171027
Classification Name	Endosseous Dental Implant	Endosseous Dental Implant
Product Code	NHA	DZE, NHA
Description		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Diameter (mm)	Ø4.5	Ø3.4 and Ø4.5
Length (mm)	10.71 and 12.71	10.1, 11.6 and 13.6
Sterile	End User Sterilization	End User Sterilization
Indications For Use	The Dentis s-Clean Abutment Mini is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.	The Dentis Dental Implant System is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.
Substantial Equivalence Comparison	The subject device has same indications for Use, fundamental scientific technology, principle of operation, technology, functions, and materials and has similar design with the primary predicate. The difference between the subject and primary predicate is the Dimensions of the device and the compatible implant body. The subject device's diameter(Ø2.88) with length (9.11mm) is smaller size than the primary predicate but doesn't affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

2. s-Clean TiN Half Coating Sub-Octa Abutment

	Subject Device	**Primary Predicate**
Applicant	Dentis Co., Ltd.	Dentis Co., Ltd.
Trade Name	Dentis s-Clean Abutment Mini	Dentis Dental Implant System
510(k) No.	-	K171027
Classification Name	Endosseous Dental Implant	Endosseous Dental Implant
Product Code	NHA	DZE, NHA
Description		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Diameter (mm)	Ø4.8	Ø4.8
Length (mm)	8.16, 8.66, 9.66, 10.66, 11.66 and 12.66	9.15, 9.65, 10.65, 11.65, 12.65 and 13.65
Surface Treatment	TiN Coating	TiN Coating
Sterile	End User Sterilization	End User Sterilization
Indications For Use	The Dentis s-Clean Abutment Mini is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.	The Dentis Dental Implant System is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.
Substantial Equivalence Comparison	The subject device has same indications for Use, fundamental scientific technology, principle of operation, technology, functions, and materials and has similar design with the primary predicate. The difference between the subject and primary predicate is the lengths of the device and the compatible implant body. The subject device has shorter size than the primary predicate but doesn't affect device's fundamental functions and safety; therefore, it is substantial equivalent.	

3. s-Clean CCM UCLA Abutment s-Line

	Subject Device	**Primary Predicate Device**	**Reference Device**
Applicant	Dentis Co., Ltd.	Dentis Co., Ltd.	Dentis Co., Ltd.
Trade Name	Dentis s-Clean Abutment Mini	Dentis Dental Implant System	s-Clean OneQ-SL Narrow Implant System
510(k) No.	-	K171027	K161244
Classification Name	Endosseous Dental Implant	Endosseous Dental Implant	Endosseous Dental Implant
Product Code	NHA	DZE, NHA	DZE, NHA
Class	Class II	Class II	Class II
Description			
Material	Cobalt-28Chromium-6Molybdenum Alloy (ASTM F1537)	Cobalt-28Chromium-6Molybdenum Alloy (ASTM F1537)	Cobalt-28Chromium-6Molybdenum Alloy (ASTM F1537)
Diameter (mm)	Ø4.0	Ø4.5	Ø4.0
Gingival Height	1mm and 3mm	1mm and 3mm	1mm
Sterile	End User Sterilization	End User Sterilization	End User Sterilization
Indications For Use/ Intended Use	The Dentis s-Clean Abutment Mini is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.	The Dentis Dental Implant System is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.	The s-Clean OneQ-SL Narrow 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 terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading. Only, s-Clean OneQ-SL Narrow fixture (3.0, 3.3, 3.7mm) is limited to replacement of maxillary lateral incisors and mandibular incisors.
Substantial Equivalence Comparison	The subject device has same indications for Use, fundamental scientific technology, principle of operation, technology, functions, and materials and has similar design with the primary predicate. The difference between the subject and primary predicate is the diameter of the device and the compatible implant body. To support this discrepancy, K161244 was added; therefore, it is substantial equivalent.		

Non-Clinical Testing

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

- Biocompatibility testing according to ISO 10993-1:2009 for Ti-6Al-4V material abutments referenced in K210080, for Cobalt-28Chrominum-6Molybdenum material abutment referenced in K161244 and for Ti-6Al-4V with TiN Coating abutments referenced in K171027
- End User Sterilization Validation Test Report according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1 referenced in K111364 for Ti-6Al-4V material abutments non-coating and TiN-Coating.

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

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

Biocompatibility testing for Ti-6Al-4V wth TiN Coating material abutments was conducted on the predicate device, K171027 and can be leveraged for the subject device because both devices have same material and manufacturing process which is substantially equivalent.

Fatigue testing was not performed for the subject device according to the ISO 14801:2016 because this subject device system does not include any angled abutments. Based on the FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", the fatigue testing is not necessary if the system does not consist of angled abutments. Also, the surface modification for the subject device was not tested or provided because the surface modification information was provided in the predicate devices and can be leveraged for the subject device.

End User Sterilization Validation Test Report for Cobalt-27Chrominum-6Molybdenum was conducted on the device that is not cleared by FDA. The test article is the largest surface area among the devices that have the same manufacturing process and material.

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

- MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the Dentis s-Clean Abutment Mini 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

Conclusion

Dentis s-Clean Abutment Mini 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, the Dentis s-Clean Abutment Mini and its predicates are substantially equivalent.