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

May 25, 2023

Re: K230246
Trade/Device Name: Dentis s-Clean SQ-SL Narrow Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 28, 2023
Received: April 28, 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)*
K230246

Device Name
Dentis s-Clean SQ-SL Narrow Implant System

Indications for Use *(Describe)*
The Dentis s-Clean SQ-SL Narrow Implant System is intended for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The Dentis s-Clean SQ-SL Narrow Implant System is limited to the replacement of maxillary lateral incisors and mandibular incisors. 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.

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510(K) Summary

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Device Information

- Trade Name: Dentis s-Clean SQ-SL Narrow Implant System
- Common Name: Dental Implant Abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date Prepared: 05/25/2023

Predicate Devices:

Primary Predicate

- K161244, s-Clean OneQ-SL Narrow Implant System

Reference devices

- K182194, UV Active Implant System manufactured by DIO Corporation
- K210080, Dentis s-Clean s-Line Mini manufactured by Dentis Co., Ltd.
- K171027, Dentis Dental Implant System by Dentis Co., Ltd.
- K171694, s-Clean TiN Coating Abutments by Dentis Co., Ltd.

Indication for Use:

The Dentis s-Clean SQ-SL Narrow Implant System may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.

The implants may be restored immediately

1) with a temporary prosthesis that is not in functional occlusion,
2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or
3) for denture stabilization using multiple implants in the anterior mandible and maxilla.

The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.

Device Description:

The Dentis s-Clean SQ-SL Narrow Implant System is used to replace missing teeth in various situations ranging from a single tooth loss to the complete loss of incisors teeth. This system is restricted to substitute the maxillary lateral incisors and mandibular incisors. It is one and two stage endosseous screw type implant with internal connection, intended for single use. Dentis s-Clean SQ-SL Narrow Implant System is a suitable treatment option when the possibility of placing a standard implant is limited due to physical conditions, where the horizontal space is limited by adjacent teeth and roots, or in situations with a narrow alveola ridge.

The dimensions of abutments are as following:

No.	Device Name	Dimension Ranges	Angulation
1	s-Clean TiN Half Coating Angled Abutment (Narrow)	Ø4.0 (D) X 10.26, 10.76, 12.26 and 12.76mm (L)	15º
2	s-Clean Temporary Abutment (Narrow)	Ø4.0 (D) X 12.5, 13, 14.5 and 15mm (L)	0º

Tolerance of dimension for Abutments shall be within ± 1% range.

The Abutments have below featured:

Name	Uses	Surface	Connection
s-Clean TiN Half Coating Angled Abutment (Narrow)	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	TiN Coating	Screw Retained
s-Clean Temporary Abutment (Narrow)	Arbitrarily shaped upper structure used to restore masticatory movement temporarily by using prosthesis made according to patient's condition	N/A	Screw Retained

The s-Clean TiN Half Coating Angled Abutment (Narrow) and s-Clean Temporary Abutment (Narrow) intended for use with the s-Clean OneQ-SL Fixture in K161244.

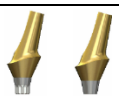
The s-Clean Temporary Abutment (Narrow) is not intended to be cast at angulation or placed to provide angular correction.

Materials:

- s-Clean TiN Half Coating Angled Abutment (Narrow) is fabricated from Ti-6Al-4V ELI of ASTM F136
- The s-Clean Temporary Abutment (Narrow) is fabricated from PEEK material.

Summaries of Technological Characteristics & Substantial Equivalence Discussion

s-Clean TiN Half Coating Angled Abutment (Narrow)

	Subject Device	Primary Predicate	Reference Predicate
K number	K230246	K161244	K182194
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.	DIO CORPORATION
Trade Name	Dentis s-Clean SQ-SL Narrow Implant System	s-Clean OneQ-SL Narrow Implant System	UV Active Implant System
Indications for Use	The Dentis s-Clean SQ-SL Narrow Implant System may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.	The s-Clean OneQ-SL Narrow Implant System may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.	The UV Active Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The narrow (Ø3.0, Ø3.3) implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. It is intended for delayed loading. The Regular (Ø3.8 ~ Ø5.5) 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 is achieved with appropriate occlusal loading. The Wide (Ø6.0 ~ Ø6.4) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.
Design		-	
Diameter	Ø4.0	-	Ø4.0, 4.5 and 5.5
Gingival Height	1.8 and 3.8mm	-	1.5, 2.0, 3.0, 4.0 and 5.0 mm
Angled	15°	-	15° and 25°
Coating	TiN Coating	-	TiN Coating
Material	Ti-6Al-4V ELI	-	Ti-6Al-4V ELI
Sterilization	End User Sterilization	-	End User Sterilization
Comparison	The subject device and reference predicate, K182194 have same intended use, material, coating and sterilization method. The differences between the two devices are dimensions and indications. The dimensions of the subject device are in range of the predicate device and the indications for use of the subject device is exactly same as the primary predicate, K161244; therefore, the subject device is substantial equivalent.		

s-Clean Temporary Abutment (Narrow)

	Subject Device	Primary Predicate	Reference Device
K number	K230246	K161244	K210080
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean SQ-SL Narrow Implant System	s-Clean OneQ-SL Narrow Implant System	Dentis s-Clean s-Line Mini
Indications for Use	The Dentis s-Clean SQ-SL Narrow Implant System may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.	The s-Clean OneQ-SL Narrow Implant System may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.	Dentis s-Clean s-Line Mini 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. This system is intended for delayed loading.
Design	 	-	 
Diameter	Ø4.0	-	Ø4.0, 4.5 and 5.5
Length	12.5, 13, 14.5 and 15 mm	-	13.45, 13.7, 15.45 and 15.7mm
Coating	Non	-	Non
Material	PEEK	-	PEEK
Sterilization	End User Sterilization	-	End User Sterilization
Comparison	The subject device and reference device, K210080 have the same material and applications and similar dimensions. The differences between two devices are lengths and indications for use. The length difference is not important factor for performance because this device is used temporarily and the indications for use of the subject device is exactly same as the primary predicate, K161244; therefore, the subject device is substantial equivalent.		

Non-Clinical Test Data

Below tests were performed on subject device:

- Fatigue Testing under the worst-case scenario according to ISO 14801:2016

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

- Biocompatibility testing on Abutment according to ISO 10993-1:2009 referenced in K171694
- End User Sterilization Validation Test Report on Abutments according to ANSI/AAMI ST79, ISO 17665-1,-2, ISO 11737-1,-2, and ISO 11138-1 referenced in K171694 and K171027

The surface modification information with TiN Coating for Abutments was provided. To compare surface modification between the subject and predicate devices, K171694 and , chemical composition, SEM, EDS, adhesion and thickness were provided, and it demonstrate the substantial equivalence.

The end user sterilization test was performed for predicate device, K171694 and K171027 and leveraged for the subject device because the product category, material, manufacturing process, facility, and packaging of both products are exactly same.

The Biocompatibility Test was conducted on the predicate device 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.

The Fatigue Testing was performed under the worst-case scenario according to ISO 14801:2016.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic Dentis SQ-SL Implant System 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

Dentis s-Clean SQ-SL Narrow Implant 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 devices. Therefore, Dentis s-Clean SQ-SL Narrow Implant System and its predicates are substantially equivalent.