June 4, 2021

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

Re: K210080
Trade/Device Name: Dentis s-Clean s-Line Mini
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 3, 2021
Received: May 6, 2021

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210080

Device Name
Dentis s-Clean s-Line Mini

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Submitter
Dentis Co., Ltd.
Gyu Ri Kim
99, Seongseoseo-ro, Dalseo-gu
Daegu, 42718 Korea
Email: kgr1026@dentis.co.kr
Tel. +82-53-589-3541
Fax. +82-53-289-7922

Official Correspondent
Withus Group Inc.
April Lee
106 Superior,
Irvine, CA 92620 USA
Email: withus6664@gmail.com
Phone: 1-909-274-9971
Fax: 1-909-460-8122

Device Information

- Trade Name: Dentis s-Clean s-Line Mini
- Common Name: Dental Implant System
- Classification Name: Endosseous dental implant
- Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date Prepared: 06/04/2021

Predicate Devices:

Primary Predicate

- K153639, Dentis Dental Implant System manufactured by Dentis Co., Ltd.

Reference devices

- K123155, Luna Dental Implant System manufactured by SHINHUNG MST Co., Ltd.
- K123988, AnyOne Internal Implant System by MegaGen implant Co., Ltd
- K150344, Dentis Dental Implant System manufactured by Dentis Co., Ltd.
- K161689, OSSTEM Implant System – Abutment by OSSTEM Implant Co., Ltd
- K171027, Dentis Dental Implant System manufactured by Dentis Co., Ltd.
- K171694, s-Clean TiN Coating Abutment manufactured by Dentis Co., Ltd.
- K192436, Healing Abutments and Cover Screws manufactured by Dentium Co., Ltd.
- K200099, s-Clean SQ-SL Implant System Mini manufactured by Dentis Co., Ltd.
- K202773, s-Clean SQ-SL Implant System Mini manufactured by Dentis Co., Ltd.

Indication for Use:
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.

Device Description:
Dentis s-Clean s-Line Mini is composed of Fixture and Abutments. s-Clean SQ-SL Fixture Mini is a thread type implant made of Pure titanium according to ASTM F67 which will be placed in the alveolar bone to replace the function of the missing tooth. This device has connection between the upper prosthesis and the internal Hex.

The subject implant body has a two screw-joint (structured with Upper and Lower screw joints) and a hex anti-rotation design connection. The two-screw-joint feature is for diverse screw connection with other abutment that has 1.6M screw or 2.0M Screw. s-Clean Sole Abutment s-Line Mini and s-Clean TiN Half Coating Sole Abutment s-Line Mini have Upper M2.0 screw and s-Clean Couple Abutment s-Line Mini, s-Clean TiN Half Coating Couple Abutment s-Line Mini, s-Clean Angled Abutment s-Line Mini and s-Clean TiN Half Coating Angled Abutment s-Line Mini have 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 surface of fixture is treated with SLA (Sandblasted with Large-grit and Acid-etching).
It is only part to be implanted into bone, and to provide connection of prosthetic devices or other components of a dental implant set with human body (mandibular or maxillary bone).

The dimensions of fixtures are as following:

No.	Device Name	Dimension Ranges
1	s-Clean SQ-SL Fixture Mini	Ø5.8, 6.8 and 7.8 (D) X 7.5, 9.5, 11.4 and 11.5mm

Tolerance of dimension shall be within ± 1% range.

The dimensions of abutments are as following:

No.	Device Name	Dimension Ranges	Angulation
1	s-Clean Cover Screw Mini	Ø3.2 (D) x 5.0mm (L)	0º
2	s-Clean Healing Abutment s-Line Mini	Ø4.3, 4.8 and 5.8 (D) X 7.61, 8.61, 9.61, 10.61, 11.61, 12.61 and 14.61mm (L)	0º
3	s-Clean Sole Abutment s-Line Mini	Ø4.5 and 5.5 (D) X 11.01, 12.01, 12.51, 13.01, 13.51, 14.01, 14.51, 15.01, 15.51, 16.01 and 17.01mm (L)	0º
4	s-Clean TiN Half Coating Sole Abutment s-Line Mini	Ø4.5 and 5.5 (D) X 11.01, 12.01, 12.51, 13.01, 13.51, 14.01, 14.51, 15.01, 15.51, 16.01 and 17.01mm (L)	0º
5	s-Clean Couple Abutment s-Line Mini	Ø4.0, 4.5 and 5.5 (D) X 8.35, 8.6, 9.35, 9.6, 9.85, 10.1, 10.35, 10.6, 10.85, 11.1, 11.35, 11.6, 11.85, 12.1, 12.35, 12.6, 12.85, 13.1, 13.35, 13.6, 14.35 and 14.6mm (L)	0º
6	s-Clean TiN Half Coating Couple Abutment s-Line Mini	Ø4.0, 4.5 and 5.5 (D) X 8.35, 8.6, 9.35, 9.6, 9.85, 10.1, 10.35, 10.6, 10.85, 11.1, 11.35, 11.6, 11.85, 12.1, 12.35, 12.6, 12.85, 13.1, 13.35, 13.6, 14.35 and 14.6mm (L)	0º
7	s-Clean Angled Abutment s-Line Mini	Ø4.0, 4.5 and 5.5 (D) X 12.09, 12.34, 12.51, 12.76, 13.09, 13.34, 13.51 and 13.76mm (L)	15˚ and 25˚
8	s-Clean TiN Half Coating Angled Abutment s-Line Mini	Ø4.0, 4.5 and 5.5 (D) X 12.09, 12.34, 12.51, 12.76, 13.09, 13.34, 13.51 and 13.76mm (L)	15˚ and 25˚
9	s-Clean Abutment Screw s-Line Mini	ø2.03 (D) X 10.2mm (L)	0º
10	s-Clean Temporary Abutment Mini	Ø4.0. 4.5 and 5.5 (D) x 13.45, 13.7, 15.45 and 15.7mm	0º
11	s-Clean MU Straight Abutment Mini	Ø4.8 (D) X 8.71, 9.71, 10.71, 11.71 and 12.71mm (L)	0º

12	s-Clean MU Angled Abutment Mini	Ø1.56 (D) X 7.25, 7.74, 8.25, 8.74, 9.25, 9.74, 10.25 and 10.74mm (L)	17˚ and 30˚
13	s-Clean MU Angled Abutment Screw Mini	Ø1.56 (D) X 9.3mm (L)	0º

The Abutments have below featured:

Name	Uses	Surface	Connection
s-Clean Cover Screw Mini	It is used for protecting inner hole and connecting part with exposed upper part of structure during the healing period after inserting dental implant fixture	Anodizing (Gold Color)	Screw Retained
s-Clean Healing Abutment s-Line Mini	The healing Abutment is used for protecting inner hole of fixture and adjusting the appropriate height during the healing period	Anodizing (Gold Color)	Screw Retained
s-Clean Sole Abutment s-Line Mini	The Abutment is connected with fixture and it supports prosthesis which restores tooth function. The Abutment is connected with fixture and it supports prosthesis which restores tooth function	N/A	Internal Hex
s-Clean TiN Half Coating Sole Abutment s-Line Mini		TiN-Coating	
s-Clean Couple Abutment s-Line Mini		N/A	Internal Hex
s-Clean TiN Half Coating Couple Abutment s-Line Mini		TiN-Coating	
s-Clean Angled Abutment s-Line Mini		N/A	Internal Hex
s-Clean TiN Half Coating Angled Abutment s-Line Mini		TiN-Coating	
s-Clean Abutment Screw s-Line Mini	This screw is used for connect fixture and abutment	N/A	Screw Retained
s-Clean Temporary Abutment Mini	This Abutment is used for prosthetic restore temporary	N/A	Internal Hex
s-Clean MU Straight Abutment Mini	MU Abutment is useful for various angulation implanted fixture and gingival angulation.	TiN-Coating	Internal Hex
s-Clean MU Angled Abutment Mini		TiN-Coating	Internal Hex
s-Clean MU Angled Abutment Screw Mini	This Screw is used for fixture and MU Angled Abutment	N/A	Screw Retained

Tolerance of dimension for Abutments shall be within ± 1% range.
The multi-unit abutments are only intended to be used in multi-unit restorations.

The purpose of Anodizing for s-Clean Cover Screw Mini and s-Clean Healing Abutment s-Line Mini is to distinguish the sizes with the naked eyes for convenience.
s-Clean SQ-SL Fixture Mini, s-Clean Cover Screw Mini and s-Clean Healing Abutment s-Line Mini are provided sterilized. And the other Abutments are provided non-sterilized.
s-Clean SQ-SL Fixture Mini is enclosed with s-Clean Cover Screw Mini in a set packing. s-Clean Cover Screw Mini is also provided separately.

Materials:

- s-Clean SQ-SL Fixture Mini, s-Clean Cover Screw Mini, s-Clean Healing Abutment s-Line Mini and s-Clean Temporary Abutment Mini are fabricated from Pure titanium of ASTM F67
- The s-Clean (TiN Half Coating) Sole Abutment s-Line Mini, s-Clean (TiN Half Coating) Couple Abutment s-Line Mini, s-Clean (TiN Half Coating) Angled Abutment s-Line Mini, s-Clean Abutment Screw s-Line Mini, s-Clean MU Straight Abutment Mini, s-Clean MU Angled Abutment Mini and s-Clean MU Angled Abutment Screw Mini are fabricated from Ti-6Al-4V of ASTM F136
- The s-Clean Temporary Abutment Mini is fabricated from PEEK material.

Summaries of Technological Characteristics & Substantial Equivalence Discussion

s-Clean SQ-SL Fixture Mini

	Subject Device	Predicate Device	Reference Device
K number	NA	K153639	K202773
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	Dentis Co., Ltd.
Trade Name	Dentis s-Clean s-Line Mini	Dentis Dental Implant System	s-Clean SQ-SL Implant System Mini
Design			
Indications for Use	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.	The OneQ-SL s-Clean 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	s-Clean SQ-SL Implant System 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.
Diameter	∅5.8, 6.8 and 7.8	∅3.7, 3.9, 4.2, 4.7, 5.2, 6.0, 7.0 and 8.0	Ø 3.7, 4.1
Length	7.5, 9.5, 11.4, 11.5mm	7, 8, 10, 12, 14mm	7.5, 9.5, 11.5, 13.5mm
Surface Treatment	SLA	SLA	SLA
Material	CP Titanium Gr4 (ASTM F67)	CP Titanium Gr4 (ASTM F67)	CP Titanium Grade4 (ASTM F67)
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, design, diameter, length, surface treatment, material, abutment connection, and sterilization. The difference between subject and primary predicate is only design of screw joint between fixture and abutment. Subject device has two screw-joint of fixture and abutment but primary predicate has only one screw-joint of fixture and abutment. This difference is mitigated through our own device, K202773. 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.		

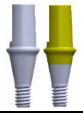
s-Clean Cover Screw Mini

	Subject Device	Reference Device	Reference Device
K number	NA	K200099	K192436
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	Dentium Co., Ltd
Trade Name	Dentis s-Clean s-Line Mini	s-Clean SQ-SL Implant System Mini	Healing Abutments and Cover Screws
Model	s-Clean Cover screw Mini	s-Clean Mini Fixture Cover screw	Cover screw
Design			
Diameter	Ø3.2	Ø3.1	Ø3.10, 3.18, 3.37, 3.50, 3.55, 4.12 and 4.30
Length	5.0mm	5.4mm	4.70, 5.40, 5.70, 5.75, 6.35, 6.36, 6.88 and 8.92mm
Coating	Anodizing (Gold Color)	Non	Anodizing (Black, Blue, Green Color) / Non
Material	Titanium Gr4 (ASTM F67)	Titanium Gr4 (ASTM F67)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	Sterile	Sterile	Sterile
Comparison	Subject Device and Reference Device, K200099 have same indications and material. The diameter and length are different from K200099, but this difference is not important factor to the device performance. Subject device is anodized to make a division according to device size. To support the surface coating and dimension differences from K200099, K192436 is added as the reference device. Therefore, the subject device is substantial equivalent.		

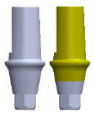
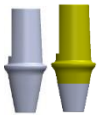
s-Clean Healing Abutment s-Line Mini

	Subject Device	Reference Device	Reference Device
K number	NA	K171027	K123155
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	SHINHUNG MST CO., Ltd
Trade Name	Dentis s-Clean s-Line Mini	Dentis Dental Implant System	Luna Dental Implant System
Model	s-Clean Healing Abutment s-Line Mini	Healing Abutment	Healing Abutment
Design			
Diameter	Ø4.3, 4.8 and 5.8	Ø4.0, 4.5, 4.8, 5.0, 5.5, 6.0, 6.5, 7.0 and 7.5	Ø4.5~7.0
Length	7.61, 8.61, 9.61, 10.61, 11.61, 12.61 and 14.61mm	9.5, 10.0, 10.5, 11.0, 11.5, 12.0, 12.5, 13.0, 13.5 and 14.0mm	2.0, 3.5, 5.0 and 7.0
Coating	Anodizing (Gold Color)	Non	Anodizing (Purple, Blue Color)
Material	Titanium Gr4 (ASTM F67)	Titanium Gr4 (ASTM F67)	Titanium Gr4 (ASTM F67)
Sterilization	Sterile	Sterile	Sterile
Comparison	Subject Device and reference device, K171027 have same Indications and material. The diameter and length are different from K171027 but this difference is not important factor to the device performance. Subject device is anodized to make a division according to device size. This difference about surface coating is explained through Reference Device, K123155. Therefore, the subject device is substantial equivalent.		

s-Clean Sole Abutment s-Line Mini & s-Clean TiN Half Coating Sole Abutment s-Line Mini

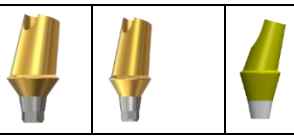
	Subject Device	Reference Device	Reference Device
K number	NA	K171694	K171027
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line Mini	s-Clean TiN Coating Abutment	Dentis Dental Implant System
Model	s-Clean Sole Abutment s-Line Mini & s-Clean TiN Half Coating Sole Abutment s-Line Mini	s-Clean TiN Partial Coating Sole Abutment	Sole Abutment
Design		 	 
Diameter	Ø4.5 and 5.5	Ø4.5, 4.8, 5.5, 6.0 and 6.5	Ø4.5, 4.8, 5.5, 6.0 and 6.5
Gingival Height	1.8, 2.8, 3.8, 4.8	0.8, 1.3, 1.8, 2.3, 3.3, 4.3 and 5.3	0.8, 1.3, 1.8, 2.3, 3.3, 4.3, and 5.3
Length	11.01, 12.01, 12.51, 13.01, 13.51, 14.01, 14.51, 15.01, 15.51, 16.01 and 17.01mm	10.6, 11.0, 11.5, 11.6, 12.0, 12.1, 12.5, 13.0, 13.1, 13.5, 13.6, 14.0, 14.1, 14.5, 15.0, 15.1, 15.5, 16.0, 16.1, 16.5, 16.6, 17.0, 17.1, 17.5, 18.1 and 18.5mm	12.5, 13.0, 13.5, 14.0, 15.0, 16.0 and 17.0mm
Coating	Non & TiN Coating	TiN Coating	Non
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Devices, K171694 and K171027 have same diameter, length, material and sterilization method. The subject device has two types of surface coating, non-coating and TiN coating. K171027 is selected for non-coating abutment and K171694 is selected for TiN coating abutment as predicates. The subject device is substantial equivalent.		

s-Clean Couple Abutment s-Line Mini & s-Clean TiN Half Coating Couple Abutment s-Line Mini

	Subject Device	Reference Device	Reference Device
K number	NA	K171694	K171027
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line Mini	s-Clean TiN Coating Abutment	Dentis Dental Implant System
Model	s-Clean Couple Abutment s-Line Mini & s-Clean TiN Half Coating Couple Abutment s-Line Mini	s-Clean TiN Half Coating Couple Abutment	Couple Abutment
Design	 	 	 
Diameter	Ø4.0, 4.5 and 5.5	Ø4.5, 4.8, 5.5, 6.0 and Ø6.5	Ø4.0, 4.5, 4.8, 5.5, 6.0 and Ø6.5
Gingival Height	1.8, 2.8, 3.8, 4.8	0.8, 1.3, 1.8, 2.3, 3.3, 4.3 and 5.3mm	0.8, 1.3, 1.8, 2.3, 3.3, 4.3 and 5.3mm
Length	8.35, 8.6, 9.35, 9.6, 9.85, 10.1, 10.35, 10.6, 10.85, 11.1, 11.35, 11.6, 11.85, 12.1, 12.35, 12.6, 12.85,	7.3, 7.44, 7.8, 7.94, 8.3, 8.44, 8.8, 8.94, 9.3, 9.44, 9.8, 9.94, 10.3, 10.44, 10.8, 10.94, 11.3, 11.44, 11.8,	7.3, 7.44, 7.8, 7.94, 8.3, 8.44, 8.8, 8.94, 9.3, 9.44, 9.8, 9.94, 10.3, 10.4, 10.44, 10.8, 10.9, 10.94, 11.3, 11.4, 11.44, 11.8,

	13.1, 13.35, 13.6, 14.35, 14.6	11.94, 12.3, 12.44, 12.8, 12.94, 13.3, 13.44, 13.8, 13.94, 14.8 and 14.94mm	11.9, 11.94, 12.3, 12.44, 12.8, 12.9, 12.94, 13.3, 13.44, 13.8, 13.9, 13.94, 14.8, 14.9 and 14.94mm
Coating	Non	TiN Coating	Non
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Devices, K171694 and K171027 have same diameter, length, material and sterilization method. The subject device has two types of surface coating, non-coating and TiN coating. K171027 is selected for non-coating abutment and K171694 is selected for TiN coating abutment as predicates. The subject device is substantial equivalent.		

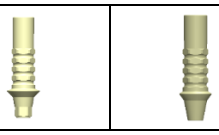
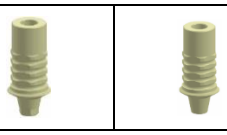
s-Clean Angled Abutment s-Line Mini & s-Clean TiN Half Coating Angled Abutment s-Line Mini

	Subject Device	Reference Device	Reference Device
K number	NA	K171694	K123988
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	MegaGemImpalnt Co., Ltd
Trade Name	Dentis s-Clean s-Line Mini	s-Clean TiN Coating Abutment	AnuOne Imternal Implant System
Model	s-Clean Angled Abutment s-Line Mini & s-Clean TiN Half Coating Angled Abutment s-Line Mini	s-Clean TiN Half Coating Angled Abutment	Angld Abutment
Design			
Diameter	Ø4.0, 4.5 and 5.5	Ø4.5, 5.0,5.5 and Ø6.5	Ø3.8~10.0
Gingival Height	2.8 and 3.8	0.8, 1.8 and 3.8mm	2.5 and 4.5mm
Length	12.09, 12.34, 12.51, 12.76, 13.09, 13.34, 13.51, 13.76,	10.18, 10.4, 10.46, 10.6, 11.18, 11.6, 12.4, 13.18 and 13.6	7.7~18.7
Angulation	15˚ and 25˚	15˚ and 25˚	15˚ and 25˚
Coating	Non	TiN Coating	TiN Coating
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Devices, K171694 and K171027 have same diameter, length, material, angulation and sterilization method. The subject device has two types of surface coating, non-coating and TiN coating. K171027 is selected for non-coating abutment and K171694 is selected for TiN coating abutment as predicates. The subject device is substantial equivalent.		

s-Clean Abutment Screw s-Line Mini

	Subject Device	Reference Device
K number	NA	K171027
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line Mini	s-Clean TiN Coating Abutment
Model	s-Clean Abutment Screw s-Line Mini	Abutment Screw
Design		
Head Diameter	Ø 2.03	Ø2.32
Length	10.2mm	8.8, 9.8, 9.95 and 10.5mm
Coating	Non	Non
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Device, K171694 have same material and applications and similar dimensions. The diameter is different but this difference is not important factor to the device performance. Therefore, the subject device is substantial equivalent.	

s-Clean Temporary Abutment Mini

	Subject Device	Reference Device	Reference Device
K number	NA	K171027	K161689
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	OSSTEM Implant Co., Ltd
Trade Name	Dentis s-Clean s-Line Mini	Dentis Dental Implant System	OSSTEM Implant System - Abutment
Model	s-Clean Temporary Abutment Mini	Temporary Abutment	Quick Temporary Abutment
Design			
Diameter	Ø4.0, 4.5, and 5.5	Ø4.5, 4.8, 5.5, 6.0 and 6.5	Ø4.0 and 4.5
Length	13.45, 13.7, 15.45 and 15.7mm	13.4 and 13.54mm	11.5mm
Coating	Non	Non	Non
Material	PEEK	PEEK	PEEK
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Device, K171027 have same material and applications and similar dimensions. Difference are lengths but this difference is not important factor for performance because this device is used for temporary and explained through Reference Device, K161689		

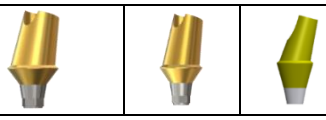
s-Clean Temporary Abutment Mini

	Subject Device	Reference Device	Reference Device
K number	NA	K171027	K161689
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	OSSTEM Implant Co., Ltd
Trade Name	Dentis s-Clean s-Line Mini	Dentis Dental Implant System	OSSTEM Implant System - Abutment
Model	s-Clean Temporary Abutment Mini	Temporary Abutment	Quick Temporary Abutment
Design			
Diameter	Ø4.0, 4.5, and 5.5	Ø4.5, 4.8, 5.5, 6.0 and 6.5	Ø4.0 and 4.5
Length	13.45, 13.7, 15.45 and 15.7mm	13.4 and 13.54mm	13.0, 13.5, 13.6, 15.0, 15.5 and 15.6mm
Coating	Non	Non	Non
Material	CP Titanium Gr4 (ASTM F67)	CP Titanium Gr4 (ASTM F67)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Device, K171027 have same material and applications and similar dimensions. Difference are diameter but this difference is not important factor for performance because this device is used for temporary and explained through Reference Device, K161689.		

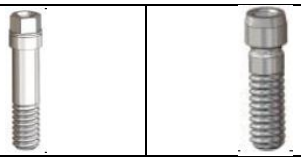
s-Clean MU Straight Abutment Mini

	Subject Device	Reference Device	Reference Device
K number	NA	K150344	K171694
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line Mini	Dentis Dental Implant System	s-Clean TiN Coating Abutment
Model	s-Clean MU Straight Abutment Mini	MU Solid Abutment	s-Clean TiN Partial Coating Sole Abutment
Design			
Diameter	Ø4.8	Ø4.8	Ø4.5, 4.8, 5.5, 6.0 and 6.5
Length	8.71, 9.71, 10.71, 11.71 and 12.71mm	4.34, 5.34, 6.08, 6.34, 6.69, 7.34, 8.08, 8.69, 9.2, 10.2, 11.2 and 12.2mm	10.6, 11.0, 11.5, 11.6, 12.0, 12.1, 12.5, 13.0, 13.1, 13.5, 13.6, 14.0, 14.1, 14.5, 15.0, 15.1, 15.5, 16.0, 16.1, 16.5, 16.6, 17.0, 17.1, 17.5, 18.1 and 18.5mm
Coating	TiN Coating	Non	TiN Coating
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Device, K150344 have same material, diameter and applications. Differences between subject device and reference device is surface coating and lengths. To support this discrepancy, K171694 is added. The length difference doesn't affect product performance because the subject device's lengths are in range of the predicate's. Therefore, the subject device is substantial equivalent.		

s-Clean MU Angled Abutment Mini

	Subject Device	Reference Device	Reference Device
K number	NA	K150344	K171694
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line Mini	Dentis Dental Implant System Multi-unit Abutments	s-Clean TiN Coating Abutment
Model	s-Clean MU Angled Abutment Mini	MU Angled Abutment	s-Clean TiN Half Coating Angled Abutment
Design			
Diameter	Ø4.8	Ø4.8	Ø4.5, 5.0,5.5 and Ø 6.5
Length	7.25, 7.74, 8.25, 8.74, 9.25, 9.74, 10.25 and 10.74mm	4.34, 5.34, 6.08, 6.34, 6.69, 7.34, 8.08, 8.69, 9.2, 10.2, 11.2 and 12.2mm	10.18, 10.4, 10.46, 10.6, 11.18, 11.6, 12.4, 13.18 and 13.6
Angulation	17˚ and 30 ˚	17˚ and 30 ˚	15˚ and 25˚
Coating	TiN Coating	Non	TiN Coating
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	End User Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Device, K150344 have same indications, material, diameter, angulation, and sterilization method. Differences between subject device and reference device is surface coating and lengths. To support this discrepancy, K171694 is added. The length difference doesn't affect product performance because the subject device's lengths are in range of the predicate's. Therefore, the subject device is substantial equivalent.		

s-Clean MU Angled Abutment Screw Mini

	Subject Device	Reference Device
K number	NA	K150344
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line Mini	Dentis Dental Implant System
Model	s-Clean MU Angled Abutment Screw Mini	MU Abutment Screw
Design		
Head Diameter	Ø1.56	Ø1.96 and 2.32
Length	9.3	7.8, 9.2, 10.2, 11.2 and 12.2mm
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Device, K150344 have same indications and material and similar dimensions. The diameter and length is different but this difference is not important factor to the device performance. 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:

- Sterilization Validation Test on Fixtures according to ISO 11137-1,2,3 referenced in K192688
- End User Sterilization Validation Test Reort on Abutments according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1 referenced in K111364
- Shelf-Life Test on Fixtures according to ASTM F1980 referenced in K153639
- Biocompatibility testing on fixtures according to ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2007, ISO 10993-10:2010 and ISO 10993-11:2006 referenced in K153639
- Biocompatibility testing on Abutments made with Ti-6Al-4V ELI according to ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2007, ISO 10993-10:2010 and ISO 10993-11:2006 referenced in K171027 and K150344
- Biocompatibility testing on TiN Coating Abutments according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010 and ISO 10993-11:2006 referenced in K171694
- Biocompatibility evaluation on abutments made with PEEK referenced in K171027
- Bacterial Endotoxin Test Report on Fixtures according to ANSI/AAMI ST72:2011, USP <161>, and USP <85> referenced in K192688

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

The surface modification information with SLA (Sandblasted with Large-grit and Acid-etching) for fixtures was provided. To compare surface modification between the subject and predicate devices, K153639, surface roughness, surface composition analysis, and SEM imaging were provided and it demonstrate the substantial equivalence.

The Sterilization validation test and shelf-life test for fixtures were performed for predicate device, K192688 and K153639 and leveraged for the subject device because the material, sterilization method, packaging methods, and manufacturing process of the both products are exactly same.

The end user sterilization test was performed for predicate device, K111364 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 and leveraged for the subject device because both products are manufactured with same materials and manufacturing process.

The fatigue testing per ISO 14801 was conducted under the worst-case scenario. To demonstrate the substantial equivalence of the device performance between single screw joint implant and dual screw joint implant, two fatigue tests were performed comparatively, and result say that device performance was substantial equivalent.

The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion

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