April 19, 2021

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

Re: K210134
Trade/Device Name: Dentis s-Clean s-Line
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 8, 2021
Received: January 19, 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 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)*
K210134

Device Name
Dentis s-Clean s-Line

Indications for Use *(Describe)*
Dentis s-Clean s-Line 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.

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510(K) Summary

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Device Information

- Trade Name: Dentis s-Clean s-Line
- Common Name: Dental Implant System
- Classification Name: implant, endosseous, root-form
- Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date Prepared: 04/19/2021

Predicate Devices:
The subject device is substantially equivalent to the following predicate devices:

Primary Predicate

- K153639, OneQ SL s-Clean Implant System manufactured by Dentis Co., Ltd.

Reference devices

- K082843, Dentis Dental Implant System manufactured by Dentis Co., Ltd
- K150344, Dentis Dental Implant System manufactured by Dentis Co., Ltd.
- K171027, Dentis Dental Implant System manufactured by Dentis Co., Ltd.
- K171694, s-Clean TiN Coating Abutment manufactured by Dentis Co., Ltd.
- K192688, s-Clean SQ-SL Implant System Regular

Indication for Use:
Dentis s-Clean s-Line 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 is composed of Fixture and Abutments. s-Clean SQ-SL Fixture 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 surface of fixture is treated with SLA (Sandblasted with Large-grit and Acid-etching).

The dimensions of fixtures are as follows:

No.	Device Name	Dimension Ranges
1	s-Clean SQ-SL Fixture	Ø5.8, 6.8 and 7.8 (D) x 7.0, 7.5, 9.5, 11.4 and 11.5mm (L)

Tolerance of dimension shall be within ± 1% range.

The dimensions of abutments are as following:

No.	Device Name	Dimension Ranges	Angulation
1	s-Clean Healing Abutment s-Line	Ø4.8, 5.8, 6.8 and 7.8 (D) x 8.2, 9.2, 10.2, 11.2, 12.2, 13.2 and 15.2mm (L)	0º
2	s-Clean Sole Abutment s-Line	Ø4.5, 5.5 and 6.5 (D) x 13.1, 14.1, 14.6, 15.1, 15.6, 16.1, 16.6 and 17.6mm (L)	0º
3	s-Clean TiN Half Coating Sole Abutment s-Line	Ø4.5, 5.5 and 6.5 (D) x 13.1, 14.1, 14.6, 15.1, 15.6, 16.1, 16.6 and 17.6mm (L)	0º
4	s-Clean Couple Abutment s-Line	Ø4.5, 5.5 and 6.5 (D) x 8.3, 8.44, 9.3, 9.44, 9.8, 9.94, 10.3, 10.44, 10.8, 10.94, 11.3, 11.44, 11.8, 11.94, 12.3, 12.44, 12.8, 12.94, 13.3 13.44, 14.3 and 14.44mm (L)	0º
5	s-Clean TiN Half Coating Couple Abutment s-Line	Ø4.5, 5.5 and 6.5 (D) x 8.3, 8.44, 9.3, 9.44, 9.8, 9.94, 10.3, 10.44, 10.8, 10.94, 11.3, 11.44, 11.8, 11.94, 12.3, 12.44, 12.8, 12.94, 13.3 13.44, 14.3 and 14.44mm (L)	0º
6	s-Clean Angled Abutment s-Line	Ø4.5, 5.5 and 6.5 (D) x 12.04, 12.18, 12.46, 12.6, 13.04, 13.18, 13.46 and 13.6mm (L)	15º, 25º
7	s-Clean TiN Half Coating Angled Abutment s-Line	Ø4.5, 5.5 and 6.5 (D) x 12.04, 12.18, 12.46, 12.6, 13.04, 13.18, 13.46 and 13.6mm (L)	15º, 25º
8	s-Clean Abutment Screw s-Line	Ø2.32 (D) x 9.4mm (L)	0º
9	s-Clean MU Straight Abutment	Ø4.8 (D) x 9.3, 10.3, 11.3, 12.3 and 13.3mm (L)	0º
10	s-Clean MU Angled Abutment	Ø4.8 (D) x 7.09, 7.58, 8.09, 8.58, 9.09, 9.58, 10.09 and 10.58mm (L)	17º, 30º
11	s-Clean MU Angled Abutment Screw	Ø1.96 (D) x 8.08mm (L)	0º
12	s-Clean MU Cylinder Screw	Ø1.97 (D) x 3.8mm (L)	0º
13	s-Clean MU Healing Cap	Ø4.8 (D) x 4.1mm (L)	0º
14	s-Clean MU Temporary Cylinder	Ø4.8 (D) x 12mm (L)	0º
15	s-Clean MU CCM Cylinder	Ø4.9 (D) x 14mm (L)	0º

The Abutments have below featured:

Name	Uses	Surface	Connection
s-Clean Healing Abutment s-Line	The healing Abutment is used for protecting inner hole of fixture and adjusting the appropriate height during the healing period	Non	Internal Hex 2.5
s-Clean Sole Abutment s-Line	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	Non	
s-Clean TiN Half Coating Sole Abutment s-Line		TiN-Coating	
s-Clean Couple Abutment s-Line		Non	
s-Clean TiN Half Coating Couple Abutment s-Line		TiN-Coating	
s-Clean Angled Abutment s-Line		Non	
s-Clean TiN Half Coating Angled Abutment s-Line		TiN-Coating	
s-Clean Abutment Screw s-Line	This screw is used for connect fixture and abutment	Non	
s-Clean MU Straight Abutment	MU Abutment is useful for various angulation implanted fixture and gingival angulation.	TiN-Coating	
s-Clean MU Angled Abutment		TiN-Coating	
s-Clean MU Angled Abutment Screw	This Screw is used for fixture and MU Angled Abutment	Non	
s-Clean MU Cylinder Screw	This Screw is used for cylinder and MU Abutment	Non	
s-Clean MU Healing Cap	This Healing cap is used for protect the abutment and reduce patient discomfort.	Non	
s-Clean MU Temporary Cylinder	This Cylinder is used for fabricating provisional restoration	Non	
s-Clean MU CCM Cylinder	This Cylinder used for screw retained prostheses	Non	

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

s-Clean SQ-SL Implant Fixture and s-Clean Healing Abutment s-Line are provided sterilized. And all other Abutments are provided non-sterilized.

Materials:

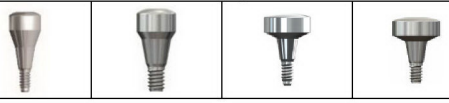
- The fixtures, s-Clean Healing Abutment s-Line, and s-Clean MU Temporary Cylinder are fabricated from Commercially Pure Titanium Grade 4 (ASTM F67).
- s-Clean Sole Abutment s-Line, s-Clean TiN Half Coating Sole Abutment s-Line, s-Clean Couple Abutment s-Line, s-Clean TiN Half Coating Couple Abutment s-Line, s-Clean Angled Abutment s-Line, s-Clean TiN Half Coating Angled Abutment s-Line, s-Clean Abutment Screw s-Line, s-Clean MU Straight Abutment, s-Clean MU Angled Abutment, s-Clean MU Angled Abutment Screw, s-Clean MU Cylinder Screw, and s-Clean MU Healing Cap are fabricated from Ti-6Al-4V (ASTM F136).
- The s-Clean MU CCM Cylinder is fabricated from Chrome-cobalt-molybdenum (CCM) alloy material (ASTM F1537).

Summaries of Technological Characteristics & Substantial Equivalence Discussion

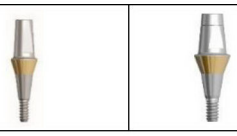
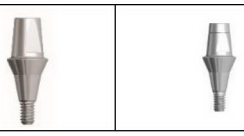
s-Clean SQ-SL Fixture

	Subject Device	**Predicate Device**
K number	NA	K153639
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line	OneQ SL s-Clean Implant System
Design		
Indications for Use	Dentis s-Clean s-Line 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. This system is intended for delayed loading.
Diameter	Ø5.8, 6.8 and 7.8	Ø3.7, 3.9, 4.2, 4.7, 5.2, 6.0, 7.0 and 8.0
Length	7.0, 7.5, 9.5, 11.4 and 11.5mm	7, 8, 10, 12 and 14mm
Surface Treatment	SLA	SLA
Material	CP Titanium Gr4 (ASTM F67)	CP Titanium Gr4 (ASTM F67)
Sterilization	Gamma sterile	Gamma sterile
Comparison	The Subject Device and Predicate Device (K153639) has same characteristics such as Indications for Use, surface treatment, material, abutment connection, and sterilization. The difference between two devices is the dimensions and external thread design. The difference in dimensions is due to the change in external thread design. Since the dimensions of the subject device are in range of the dimensions of the predicate, it doesn't impact device performance. Therefore, subject device and predicate device are substantially equivalent.	

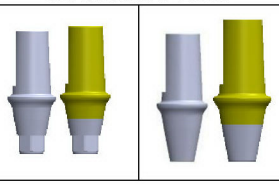
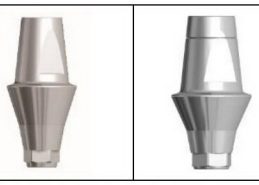
s-Clean Healing Abutment s-Line

	Subject Device	Reference Device
K number	NA	K171027
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line	Dentis Dental Implant System
Model Name	s-Clean Healing Abutment s-Line	s-Clean Healing Abutment
Design		
Diameter	Ø4.8, 5.8, 6.8 and 7.8	Ø4.0, 4.5, 4.8, 5.0, 5.5, 6.0, 6.5, 7.0 and 7.5
Length	8.2, 9.2, 10.2, 11.2, 12.2, 13.2 and 15.2mm	9.5, 10.0, 10.5, 11.0, 11.5, 12.0, 12.5, 13.0, 13.5 and 14.0mm
Coating	Non	Non
Material	Titanium Gr4 (ASTM F67)	Titanium Gr4 (ASTM F67)
Sterilization	Sterile	Sterile
Comparison	Subject Device and Reference Device, K171027 have same indication for use and material. The diameter and length are different but this difference is not important factor to the device performance. Therefore, subject device and predicate device are substantially equivalent.	

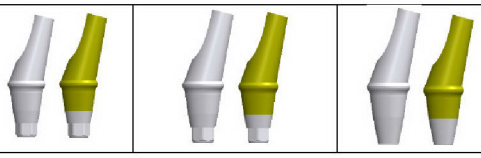
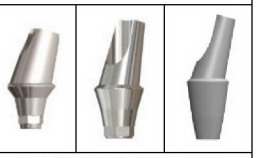
s-Clean Sole Abutment s-Line & s-Clean TiN Half Coating Sole Abutment s-Line

	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	s-Clean TiN Coating Abutment	Dentis Dental Implant System
Model name	s-Clean Sole Abutment s-Line / s-Clean TiN Half Coating Sole Abutment s-Line	s-Clean TiN Partial Coating Sole Abutment	s-Clean Sole Abutment
Design			
Diameter	Ø4.5, 5.5 and 6.5	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 and 4.8mm	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	13.1, 14.1, 14.6, 15.1, 15.6, 16.1, 16.6 and 17.6mm	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 indications sterilization and material, and similar dimensions. 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 & s-Clean TiN Half Coating Couple Abutment s-Line

	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	s-Clean TiN Coating Abutment	Dentis Dental Implant System
Model Name	s-Clean Couple Abutment s-Line / s-Clean TiN Half Coating Couple Abutment s-Line	s-Clean TiN Half Coating Couple Abutment	s-Clean Couple Abutment
Design			
Diameter	Ø4.5, 5.5 and 6.5	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 and 4.8mm	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	8.3, 8.44, 9.3, 9.44, 9.8, 9.94, 10.3, 10.44, 10.8, 10.94, 11.3, 11.44, 11.8, 11.94, 12.3, 12.44, 12.8, 12.94, 13.3 13.44, 14.3 and 14.44mm	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, 11.94, 12.3, 12.44, 12.8, 12.94, 13.3, 13.44, 13.8, 13.94, 14.8 and 14.94mm	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, 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	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 indications sterilization and material, and similar dimensions. 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 & s-Clean TiN Half Coating Angled Abutment s-Line

	Subject Device	Reference Device	Reference Device
K number	NA	K171694	K082843
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line	s-Clean TiN Coating Abutment	s-Clean TiN Coating Abutment
Model Name	s-Clean Angled Abutment s-Line / s-Clean TiN Half Coating Angled Abutment s-Line	s-Clean TiN Half Coating Angled Abutment	s-Clean Angled Abutment
Design			
Diameter	Ø4.5, 5.5 and 6.5	Ø4.5, 5.0,5.5 and Ø6.5	Ø4.5, 5.0,5.5 and Ø6.5
Gingival Height	2.8 and 3.8	0.8, 1.8 and 3.8mm	1.8 and 3.8mm
Length	12.04, 12.18, 12.46, 12.6, 13.04, 13.18, 13.46 and 13.6mm	10.18, 10.4, 10.46, 10.6, 11.18, 11.6, 12.4, 13.18 and 13.6	10.54 and 12.54mm
Angulation	15˚ and 25˚	15˚ and 25˚	15˚ and 25˚
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 K082843 have same indications sterilization and material, and similar dimensions. The subject device has two types of surface coating, non-coating and TiN coating. K082843 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

	Subject Device	Reference Device
K number	NA	K171027
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line	s-Clean TiN Coating Abutment
Model Name	s-Clean Abutment Screw s-Line	s-Clean Abutment Screw
Design		
Head Diameter	Ø2.32	Ø2.32
Length	9.4mm	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, K171027 have same indications for use, diameter, and material. The difference between two devices is the length, however it doesn't impact device performance. The subject device is substantial equivalent.	

s-Clean MU Straight Abutment

	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	Dentis Dental Implant System	s-Clean TiN Coating Abutment
Model Name	s-Clean MU Straight Abutment	MU Solid Abutment / MU Couple Abutment	s-Clean TiN Half Coating Couple Abutment
Design		 	 
Diameter	Ø4.8	Ø4.8	Ø4.5, 4.8, 5.5, 6.0 and Ø6.5
Length	9.3, 10.3, 11.3, 12.3 and 13.3mm	6.08, 8.08, 6.69, 8.69, 9.2, 10.2, 11.2 and 12.2mm	Cuff-2, 37.3, 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, 11.94, 12.3, 12.44, 12.8, 12.94, 13.3, 13.44, 13.8, 13.94, 14.8 and 14.94mm, 4, 5mm
Coating	TiN Coating	Non	TiN Coatring
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,diameter, angulation, material and sterilization method. Differences are length and coating. But the coating feature is explained with Reference Device, K71694 that has same TiN coating and the length of the subject device is in range of the length of K171694. Thus, the subject device is substantial equivalent.		

s-Clean MU Angled Abutment

	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	Dentis Dental Implant System	s-Clean TiN Coating Abutment
Model Name	s-Clean MU Angled Abutment	MU Angled Abutment	s-Clean TiN Half Coating Angled Abutment
Design			  
Diameter	Ø4.8	Ø4.8	Ø4.5, 5.0,5.5 and Ø6.5
Length	7.09, 7.58, 8.09, 8.58, 9.09, 9.58, 10.09 and 10.58mm	6.08, 8.08, 6.69 and 8.69mm	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	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, diameter, angulation, material and sterilization method. Differences are length and coating. But the coating feature is explained with Reference Device, K71694 that has same TiN coating and the length of the subject device is in range of the length of K171694. Thus, the subject device is substantial equivalent.		

s-Clean MU Angled Abutment Screw

	Subject Device	Reference Device
K number	NA	K150344
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line	Dentis Dental Implant System
Model Name	s-Clean MU Angled Abutment Screw	MU Abutment Screw
Design		 
Head Diameter	Ø1.96	Ø1.96 and 2.32
Length	8.08	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 for use and material. The diameter and length are different but this difference is not important factor to the device performance. The subject device is substantial equivalent.	

s-Clean MU Cylinder Screw

	Subject Device	Reference Device
K number	NA	K150344
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line	Dentis Dental Implant System
Model Name	s-Clean MU Cylinder Screw	s-Clean Retaining Screw
Design		
Head Diameter	ø1.97	ø1.98
Length	3.8mm	3.7mm
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	Steam sterilization by User	Steam sterilization by User
Comparison	Subject Device and Reference Device, K150344 have same indications for use and material. The diameter and length are different but this difference is not important factor to the device performance. The subject device is substantial equivalent.	

s-Clean MU Healing Cap

	Subject Device	Reference Device
K number	NA	K150344
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line	Dentis Dental Implant System
Model Name	s-Clean MU Healing Cap	MU Healing Cap
Design		
Diameter	Ø4.8	Ø5.4
Length	4.1mm	5.0mm
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 for use and material. The diameter and length are different but this difference is not important factor to the device performance. The subject device is substantial equivalent.	

s-Clean MU Temporary Cylinder

	Subject Device	**Reference Device**
K number	NA	K150344
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line	Dentis Dental Implant System
Model Name	s-Clean MU Temporary Cylinder	MU Temporary Cylinder
Design		
Diameter	Ø 4.8	Ø 4.8
Length	12mm	10.0mm
Material	CP Titanium Gr4 (ASTM F67)	CP Titanium Gr4 (ASTM F67)
Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Device, K150344 have same indications, diameter and material. The length is different but this difference is not important factor to the device performance because this device is used temporary. The subject device is substantial equivalent.	

s-Clean MU CCM Cylinder

	Subject Device	**Reference Device**
K number	NA	K150344
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean s-Line	Dentis Dental Implant System
Model Name	s-Clean MU CCM Cylinder	MU CCM Cylinder
Description		
Diameter	Ø4.9	Ø4.8
Length	14mm	14.25mm
Material	Body : Cobalt-Chrome-molybdenum Alloy (ASTM F1537) Sleeve: Acetal	Body : Cobalt-Chrome-molybdenum Alloy (ASTM F1537) Sleeve : Acetal
Sterilization	Steam sterilization by User	Steam sterilization by User
Comparison	Subject Device and Reference Device, K150344 have same indications and material. The diameter and length are different but this difference is not important factor to the device performance. The subject device is substantial equivalent.	

Performance Data

Dynamic fatigue and static strength tests were conducted according to the FDA guidance document "*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form EndosseousDental Implants and Endosseous Dental Abutments*" and ISO 14801:2016, "*Dentistry – Implants – Dynamic fatigue test for endosseous dental implants"* under the worst-case scenario.

Surface modification information according to the recommendations of the FDA guidance document, "*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments",* was leveraged from prior clearances.

The SLA (Sandblasted with Large-grit and Acid-etching) surface modification for the fixtures is identical to the primary predicate K153639. Thus, SLA (Sandblasted with Large-grit and Acid-etching) surface modification information to evaluate the fixture surface characteristics after SLA treatment (i.e., EDX chemical analysis of the surface, Scanning Electron Microscope analysis), was leveraged from the primary predicate K153639.

The subject device TiN coating for the subject s-Clean TiN Half Coated Abutments is identical to the surface treatment for the reference device, K171694. Thus, TiN (Titanium Nitride) coating information (i.e., EDS chemical composition analysis, scanning electron microscopy analysis, surface roughness, coating thickness and porosity, adhesion) was leveraged from the reference device, K171694.

Biocompatibility Testing

Biological assessment has been performed according to ISO 10993-1:2009, "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,*" and to the FDA Guidance document, "*Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food andDrug Administration Staff"*, Document issued on: June 16, 2016", for each of the subject devices.

The subject devices have equivalent nature of body contact, contact duration, material formulation, and sterilization methods compared to the primary predicate and reference devices, therefore, no new issues regarding biocompatibility were raised.

Sterilization Validation and Packaging

The sterilization process for the Dentis s-Clean s-Line Implant system as recommended in the labeling was validated according to:

For devices delivered sterile (Dentis s-Clean s-Line implants and Healing abutments) - a sterility assurancelevel (SAL) of 10^{-6} have been validated in accordance with ISO 11137-1:2006, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

The validation method used was the bioburden method in accordance with ISO 11137-2:2013, Sterilizationof health care products – Radiation – Part 2: Establishing the sterilization dose. Shelf Life validation was performed in accordance with ASTM F1980, Standard Guide for Accelerated Aging of Sterile Medical Device Packages. The worst-case construct was tested, and results demonstrated equivalence to the predicate devices. The shelf life for devices provided sterile is 8 years. The devices will not be marketed as non-pyrogenic.

Pyrogenicity information provided is based on FDA Guidance on "*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile*, issued on 21 January 2016." The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on a blood contacting and implanted device.