7/11/2023

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

Re: K230307
Trade/Device Name: Dentis i-Clean System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 11, 2023
Received: June 12, 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,

Sherrill Lathrop Blitzer

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230307

Device Name
Dentis i-Clean System

Indications for Use *(Describe)*
Dentis i-Clean 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.

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 i-Clean System
- Common Name: Dental Implant System
- Classification Name: Endosseous dental implant abutment
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date Prepared: 07/10/2023

Predicate Devices:

Primary Predicate

- K210134, Dentis s-Clean s-Line by Dentis Co., Ltd.

Reference devices

- K111364, HAPTITE COATING IMPLANT SYSTEM by Dentis Co., Ltd.
- K150344, Dentis Dental Implant System by Dentis Co., Ltd.
- K171027, Dentis Dental Implant System manufactured by Dentis Co., Ltd.
- K173120, CCM Abutment System by InnoBiosSurg Co., Ltd
- K181137, IT-III active System manufactured by Neobiotech Co., Ltd.

Indications for Use:

Dentis i-Clean 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.

Device Description:

Dentis i-Clean system is intended for use as an aid in prosthetic restoration. It consists of Abutments and Abutment screws.

Dentis i-Clean Abutments are compatible with the fixtures below:

No.	Device Name	Dimension Ranges			
1	i-Clean OneQ-SL Fixture (K142313)	Platform Diameter	Implant Nominal Diameter	Implant Apical Diameter	Length Available
		Ø6.5	Ø4.7	Ø4.2	7, 8, 10, 12, 14
			Ø5.2	Ø4.7	7, 8, 10, 12, 14
			Ø6.0	Ø4.8	7, 8, 10, 12
			Ø7.0	Ø5.75	7, 8, 10, 12

Tolerance of dimension shall be within ± 1% range.

The dimensions of abutments are as following:

No.	Device Name	Dimension Ranges	Angulation
1	i-Clean Angled Abutment	Ø3.7 and 4.3 (D) x 9.4 and 9.6mm (L)	15º and 25º
2	i-Clean Temporary Abutment	Ø6.9 (D) x 12.85, 13.85, 14.85 and 15.85mm (L)	0º
3	i-Clean CCM UCLA Abutment	Ø5.1, 6.3 and 6.8 (D) x 14.95 and 15.05mm (L)	0º
4	i-Clean Octa CCM Cylinder	Ø5.0, 6.3 and 6.8 (D) x 12.45 and 12.65mm (L)	0º
5	i-Clean Abutment Screw	Ø1.96 (D) x 7.7mm (L)	0º
6	Octa Abutment Connector Screw	Ø1.96 (D) x 4.7mm (L)	0º
7	i-Clean Cylinder Screw	Ø2.5 (D) x 4.5mm (L)	0º

i-Clean Octa CCM cylinder is intended to be used with the straight i-Clean Octa Abutment cleared in K171027.

The Abutments have below featured:

Name	Uses	Surface	Connection
i-Clean Angled Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	Non	Internal 3.1 Octa
i-Clean Temporary Abutment	The Abutment is used for fabricating a temporary provisional restoration.	Non	
i-Clean CCM UCLA Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	Non	
i-Clean Octa CCM Cylinder	The Abutment is connected with straight i-Clean Octa Abutment (cleared in K171027) to support prosthesis which restores tooth function.	Non	
i-Clean Abutment Screw	This screw is used for connecting the fixture and abutment	Non	Screw retained
Octa Abutment Connector Screw		Non	
i-Clean Cylinder Screw		Non	

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

Abutments are provided non-sterilized and must be steam sterilized by the end user before placement.

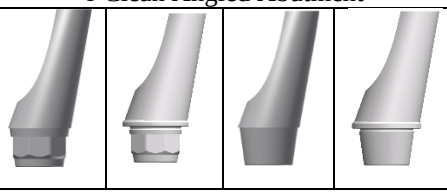
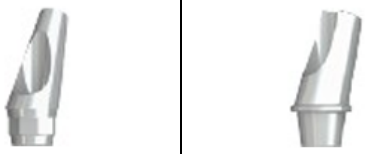
Materials:

- i-Clean Angled Abutment, i-Clean Abutment screw, Octa Abutment Connector Screw, and i-Clean Cylinder screw are fabricated from Ti-6Al-4V of ASTM F136
- i-Clean Temporary Abutment is fabricated from Polyetheretherketone (PEEK) ASTM F2026
- i-Clean CCM UCLA Abutment and i-Clean Octa CCM Cylinder is fabricated from Chrome-cobalt-molybdenum (CCM) alloy material ISO5832 and Acetal (POM)

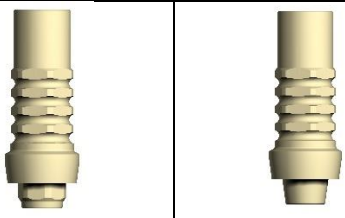
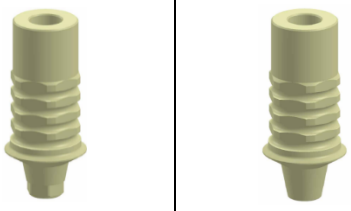
Summaries of Technological Characteristics & Substantial Equivalence Discussion

	Subject Device	**Primary Predicate**
K number	K230307	K210134
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis i-Clean System	Dentis s-Clean s-Line
Indications for Use	Dentis i-Clean 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.	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.
Comparison	The subject device and primary predicate, K210134 have same indication for use. There is no difference, therefore, both devices are substantially equivalent.	

i-Clean Angled Abutment

	Subject Device	**Reference Device**
K number	K230307	K181137
Manufacturer	Dentis Co., Ltd	Neobiotech Co., Ltd
Trade Name	Dentis i-Clean System	IT-III active System
Product Name	i-Clean Angled Abutment	IT Pre Angled Abutment
Design		
Diameter	Ø3.7 and 4.3	Ø3.7 and 4.3
Length	9.4, 9.55 and 9.6mm	9.5 and 9.68
Angle	15º and 25º	15º and 25º
Coating	Non	Non
Material	Ti-6AL-4V ELI (ASTM F136)	Ti-6AL-4V ELI (ASTM F136)
Sterilization	End-User Sterile	End-User Sterile
Comparison	The subject device and reference Device (K181137) have same indication for use, diameter, angulation, coating, material, and sterilization method. The length between two devices are different, however, it does not affect the device performance, therefore, subject device and predicate device are substantially equivalent.	

i-Clean Temporary Abutment

	Subject Device	Reference Device
K number	K230307	K171027
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis i-Clean System	Dentis Dental Implant System
Product Name	i-Clean Temporary Abutment	s-Clean Temporary Abutment
Design		
Diameter	Ø6.9	Ø4.5, 4.8, 5.5, 6.0 and 6.5
Length	12.85, 13.85, 14.85 and 15.85mm	13.4 and 13.54
Material	PEEK	PEEK
Angulation	0º	0º
Sterilization	End-user Sterile	End-user Sterile
Comparison	The subject device and reference device (K171027) have same indication for use, material, and sterilization method. The diameter and length are different, but this difference is not important factor to the device performance because they are used temporarily. Therefore, subject device and predicate device are substantially equivalent.	

i-Clean CCM UCLA Abutment

	Subject Device	Reference Device
K number	K230307	K173120
Manufacturer	Dentis Co., Ltd	InnoBioSurg. Co., Ltd
Trade Name	Dentis i-Clean System	CCM Abutment System
Product Name	i-Clean CCM UCLA Abutment	UCLA Abutment
Design		
Diameter	Ø5.1, 6.3 and 6.8	Ø4.0, 4.5, 5.0, 5.5 and 6.0
Length	14.95 and 15.05	14, 15,16 and 17mm
Material	Body:CCM, Sleeve:POM	Body:CCM, Sleeve:POM
Angulation	0º	0º
Minimum Post Heights after end user modification	4mm	4mm
Sterilization	End-user Sterile	End-user Sterile
Comparison	The subject device and reference device, K173120 have same indication for use, material, and sterilization method. The dimensions between two devices are different but this difference is not important factor to the device performance because sleeve part is cutting by end-user. Therefore, subject device and predicate device are substantially equivalent.	

i-Clean Octa CCM Cylinder

	Subject Device	Reference Device
K number	K230307	K173120
Manufacturer	Dentis Co., Ltd	InnoBioSurg. Co., Ltd
Trade Name	Dentis i-Clean System	CCM Abutment System
Product Name	i-Clean Octa CCM Cylinder	UCLA Abutment
Design		
Diameter	Ø5.0, 6.3 and 6.8	Ø4.0, 4.5, 5.0, 5.5 and 6.0
Length	12.45 and 12.65	14, 15,16 and 17mm
Material	Body:CCM, Sleeve:POM	Body:CCM, Sleeve:POM
Angulation	0º	0º
Sterilization	End-user Sterile	End-user Sterile
Comparison	The subject device and reference device, K173120 have same indication for use, material, and sterilization method. The dimensions between two devices are different but this difference is not important factor to the device performance because sleeve part is cutting by end-user. Therefore, subject device and predicate device are substantially equivalent.	

Octa Abutment Connector Screw

	Subject Device	Reference Device
K number	K230307	K210134
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis i-Clean System	Dentis s-Clean s-Line
Model Name	Octa Abutment Connector Screw	s-Clean Abutment Screw s-Line
Design		
Head Diameter	Ø2.5	Ø2.32
Length	4.7mm	9.4mm
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterilization	End-user Sterile	End-user Sterile
Comparison	The subject device and reference device (K210134) have same indication for use, material, and sterilization method. 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.	

i-Clean Abutment Screw

	Subject Device	Reference Device
K number	NA	K210134
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis i-Clean System	Dentis s-Clean s-Line
Model Name	Octa Abutment Connector Screw	s-Clean Abutment Screw s-Line
Design		
Head Diameter	Ø2.5	Ø2.32
Length	7.7mm	9.4mm
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterilization	End-user Sterile	End-user Sterile
Comparison	The subject device and reference device (K210134) have same indication for use, material, and sterilization method. 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.	

i-Clean Cylinder Screw

	Subject Device	Reference Device
K number	NA	K210134
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis i-Clean System	Dentis s-Clean s-Line
Model Name	i-Clean Cylinder Screw	s-Clean Abutment Screw s-Line
Design		
Head Diameter	Ø2.5	Ø2.32
Length	4.5mm	9.4mm
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterilization	End-user Sterile	End-user Sterile
Comparison	The subject device and reference device (K210134) have same indication for use, material, and sterilization method. 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.	

Non-Clinical Test Data

Below tests were performed on subject device:

- Fatigue Testing under the worst-case scenario according to ISO 14801:2016
- End user Sterilization Validation for Abutment made of PEEK and CCM materials according to ISO 17665-1,-2, and ISO 11737-1.

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

- End User Sterilization Validation for Abutments made of Ti-6Al-4V ELI according to ISO 17665-1,-2, and ISO 11737-1 referenced in K111364
- Biocompatibility testing on Abutments made of Ti-6Al-4V ELI according to ISO 10993-1:2009 referenced in K171027 and K150344
- Biocompatibility testing on Abutments made of PEEK and CCM according to ISO 10993-1:2009 referenced in K171027

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

For all subject devices delivered non-sterile to be end-user sterilized, the recommended sterilization has been validated according to ISO 17665-1 and ISO 17665-2 and to applicable recommendations in the FDA guidance document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015”. The worst-case construct was tested.

The Biocompatibility test was conducted on the predicate device and leveraged for the subject device because both products are manufactured with the same materials and manufacturing process. It demonstrates that the subject device is substantially equivalent with the predicate.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (e.g.,Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal

Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition.
Rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” including magnetically induced displacement force and torque.

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

Conclusion

Dentis i-Clean 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 predicate device. Therefore, Dentis i-Clean System and its predicate are substantially equivalent.