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

August 4, 2023

Re: K230126
Trade/Device Name: Dentis s-Clean Regular Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 5, 2023
Received: July 6, 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)*
K230126

Device Name
Dentis s-Clean Regular Abutment

Indications for Use *(Describe)*
Dentis s-Clean Regular Abutment 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 Regular Abutment
- 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: 08/04/2023

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

Primary Predicate

- K171027, Dentis Dental Implant System manufactured by Dentis Co., Ltd.

Reference devices

- K082843, Dentis Dental Implant System manufactured by Dentis Co., Ltd
- K111364, HAPTITE COATING IMPLANT SYSTEM by Dentis Co., Ltd.
- K150344, Dentis Dental Implant System manufactured by Dentis Co., Ltd.
- K161689, OSSTEM Implant System manufactured by Osstem Implant Co., Ltd
- K171694, s-Clean TiN Coating Abutment manufactured by Dentis Co., Ltd.
- K210134, Dentis s-Clean s-Line manufactured by Dentis Co., Ltd.
- K210826, Healing Abutment, Cover Screw manufactured by Megagen Implant Co., Ltd.
- K222913, s-Clean Link Abutment by Dentis Co., Ltd.

Indication for Use:
Dentis s-Clean Regular Abutment 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 Regular Abutment is intended for use as an aid in prosthetic restoration. It consists of Abutments, components, and Abutment screws.

Dentis s-Clean Regular Abutment is compatible with the fixtures below:

K number	Device Name	Dimension Ranges
K192688	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 Couple Abutment	Ø4.5, 5.5 and 6.5 (D) x 7.3, 7.44, 7.8, 7.94, 8.3, 8.44, 8.8, 8.94, 9.8, 9.94, 10.8 10.94, 11.8 and 11.94mm (L)	0°
2	s-Clean Angled Abutment	Ø4.5, 5.5 and 6.5 (D) x 9.4, 9.54, 10.4, 10.54, 12.4 and 12.54mm (L)	15° and 25°
3	s-Clean Temporary Abutment	Ø4.5 and 5.5 (D) x 15.4 and 15.54mm (L)	0°
4	s-Clean MU Angled Abutment	Ø4.8 (D) x 6.1mm (L)	17°
5	s-Clean MU Healing Cap	Ø5.8 and 6.8 (D) x 4.1mm (L)	0°
6	s-Clean Multi Use Coping Healing Cap	Ø5.2, 5.9 and 6.9 (D) x 6.1mm (L)	0°
7	O-Ring Abutment Retainer Cap	Ø5.15 (D) x 4.3mm (L)	0°
8	O-Ring Abutment O-Ring	Ø4.4 and 4.6 (D) x 1.5mm (L)	0°
9	SAVE Wide Cap	Ø6.0, 7.0 and 8.0 (D) x 7.7, 8.6 and 9.6mm L)	0°

The Abutments have below featured:

Name	Uses	Surface	Connection
s-Clean Couple Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	Non	Internal Hex 2.5
s-Clean Angled Abutment		Non	
s-Clean Temporary Abutment	This Abutment is used for fabricating provisional restoration	Non	
s-Clean MU Angled Abutment	MU Abutment is useful for various angulation implanted fixture and gingival angulation. MU Angled Abutment is for multi-unit only.	Non	
s-Clean MU Healing Cap	This Healing cap is used for protect the abutment and reduce patient discomfort.	Non	Screw retained
s-Clean Multi Use Coping Healing Cap		Non	N/A
O-Ring Abutment Retainer Cap	This O-Ring Abutment is used for overdenture	Non	N/A
O-Ring Abutment O-Ring		Non	N/A
SAVE Wide Cap	SAVE Wide Cap is intended for use as an aid in prosthetic rehabilitation.	Non	Screw retained

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

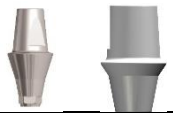
Dentis s-Clean Regular Abutment is provided non-sterilized. The SAVE Wide Cap is provided sterilized.

Materials:

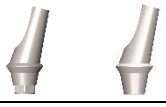
- s-Clean Couple Abutment, s-Clean Angled Abutment, s-Clean MU Angled Abutment, s-Clean MU Healing Cap and SAVE Wide Cap are fabricated from Ti-6Al-4V of ASTM F136
- s-Clean Temporary Abutment and O-Ring Abutment Retainer Cap are fabricated from Pure Titanium for ASTM F67
- s-Clean Temporary Abutment is fabricated form Polyetheretherketone for ASTM F2026
- s-Clean Multi Use Coping Healing Cap is fabricated from Polyoxymethylene(POM) for ASTM F1855

Summaries of Technological Characteristics & Substantial Equivalence Discussion

Dentis s-Clean Couple Abutment

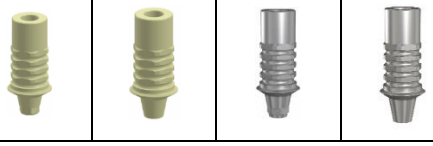
	Subject Device	**Primary Predicate**
K number	K230126	K171027
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean Regular Abutment	Dentis Dental Implant System
Product Name	s-Clean Couple Abutment	s-Clean Couple Abutment
Design		
Diameter	Ø4.5, 5.5 and 6.5	Ø4.0, 4.5, 4.8, 5.5, 6.0 and Ø6.5
Gingival Height	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	7.3, 7.44, 7.8, 7.94, 8.3, 8.44, 8.8, 8.94, 9.8, 9.94, 10.8 10.94, 11.8 and 11.94mm	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
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Primary Predicate(K171027) have same indications for use, similar sizes such as diameters, gingival heights, and lengths, material, and sterilization method. Both devices are substantial equivalent.	

s-Clean Angled Abutment

	Subject Device	**Reference Device**
K number	K230126	K082843
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean Regular Abutment	s-Clean TiN Coating Abutment
Product Name	s-Clean Angled Abutment	s-Clean Angled Abutment
Design		
Diameter	Ø4.5, 5.5 and Ø6.5	Ø4.5, 5.0,5.5 and Ø6.5
Gingival Height	0.8, 1.8 and 3.8mm	1.8 and 3.8mm
Length	9.4, 9.54, 10.4, 10.54, 12.4 and 12.54mm	10.54 and 12.54mm
Angulation	15˚ and 25˚	15˚ and 25˚
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 (K082843) have same indications for use, size as diameter, gingival height, angulation, material, and sterilization method. The lengths of the devices are different, but this difference is not an important factor for the device performance. Thus, both devices are substantial equivalent.

s-Clean Temporary Abutment

	Subject Device	**Primary Predicate**
K number	K230126	K171027
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean Regular Abutment	Dentis Dental Implant System
Product Name	s-Clean Temporary Abutment	s-Clean Temporary Abutment
Design		
Diameter	Ø4.5 and Ø 5.5	Ø4.5, 4.8, 5.5, 6.0 and Ø6.5
Length	15.4 and 15.54mm	13.4 and 13.54mm
Material	Pure Titanium Gr4 (ASFM F67) / PEEK	Pure Titanium Gr4 (ASFM F67) / PEEK
Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Primary Predicate (K171027) have same indications for use, diameters, material, and sterilization method. Difference is only length, however, this difference is not importance factor for this product because this is used temporary. Both devices are substantial equivalent.	

s-Clean MU Angled Abutment

	Subject Device	**Reference Device**
K number	K230126	K150344
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean Regular Abutment	Dentis Dental Implant System
Product Name	s-Clean MU Angled Abutment	MU Angled Abutment
Design		
Diameter	Ø4.8	Ø4.8
Length	6.1mm	6.08, 8.08, 6.69 and 8.69mm
Angulation	17˚	17˚ and 30 ˚
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, diameter, length, angulation, material, and sterilization method. Thus, both devices are substantial equivalent.	

s-Clean MU Healing Cap

	Subject Device	Reference Device
K number	K230126	K210134
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean Regular Abutment	Dentis s-Clean s-Line
Product Name	s-Clean MU Healing Cap	s-Clean MU Healing Cap
Design		
Head Diameter	Ø5.8 and 6.8	Ø4.8
Length	4.1mm	4.1mm
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 an important factor for the device performance. Thus, both devices are substantial equivalent.	

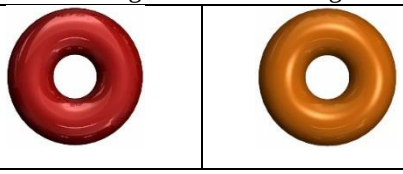
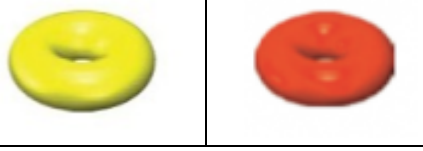
s-Clean Multi Use Coping Healing Cap

	Subject Device	Reference Device
K number	K230126	K171694
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	Dentis s-Clean Regular Abutment	s-Clean TiN Coating Abutments
Product Name	s-Clean Multi Use Coping Healing Cap	Sole Healing Cap
Design		
Head Diameter	Ø5.2, 5.9 and 6.9	Ø4.6, 5.1, 5.9, 6.3, 6.8 and 6.9
Length	6.1mm	6.7, 7.5 and 9.0mm
Material	POM	POM
Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Device (K171694) have same indications for use and material. The diameter and length are different but this difference is not an important factor for the device performance. Thus, both devices are substantial equivalent.	

O-Ring Abutment Retainer Cap

	Subject Device	Reference Device
K number	K230126	K161689
Manufacturer	Dentis Co., Ltd	Osstem Implant Co., Ltd
Trade Name	Dentis s-Clean Regular Abutment	Osstem Abutment System-Abutment
Product Name	O-Ring Abutment Retainer Cap	O-ring Retainer Cap Set
Design		
Head Diameter	Ø5.15	Ø5.0
Length	4.3mm	3.9mm
Material	Pure Titanium Gr4 (ASTM F136)	Titanium
Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Device (K161689) have same indications for use, similar sizes and material. The diameter and length are slightly different, but this difference is not an important factor for the device performance. Both devices are substantial equivalent.	

O-Ring Abutment O-Ring

	Subject Device	**Reference Device**
K number	K230126	K161689
Manufacturer	Dentis Co., Ltd	Osstem Implant Co., Ltd
Trade Name	Dentis s-Clean Regular Abutment	Osstem Abutment System-Abutment
Product Name	O-Ring Abutment O-Ring	O-ring Retainer Cap Set
Design		
Diameter	Ø4.4 and 4.6	Ø4.6
Length	1.5mm	1.5 mm
Material	Silicon	NBR(Acrylonitrile & Butadiene Polymer)
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and Reference Device (K161689) have same indications for use, length, and sterilization method. The diameter and material are different but both devices are not patient contact, and it is not important factor to the device performance. The subject device is substantial equivalent	

SAVE Wide Cap

	Subject Device	**Reference Device**
K number	K230126	K210826
Manufacturer	Dentis Co., Ltd	MegaGen Implant Co., Ltd.
Trade Name	Dentis s-Clean Regular Abutment	Healing Abutment, Cover Screw
Product Name	SAVE Wide Cap	Cover Screw
Design		
Diameter	Ø6.0, 7.0 and 8.0	Ø6.0
Length	7.7, 8.6 and 9.6mm	7.2~8.3mm
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf Life	8years	5years
Comparison	Subject Device and Reference Device (K210826) have same indications for use and material. The diameter and length are different, but this difference is not important factors for the device performance. Both devices are 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 for SAVE Wide Cap according to ISO 11137-1,2,3
- Shelf Life Test for SAVE Wide Cap according to ASTM F1980 referenced in K171027
- End User Sterilization Validation Test Report for Abutments made with Ti-6Al-4V ELI according to ANSI/AAMI ST79, ISO 17665-1,-2, ISO 11737-1,-2, and ISO 11138-1 referenced in K111364
- End User Sterilization Validation Test Report for Abutments made with PEEK, POM and CP Titanium Grade 4 according to ANSI/AAMI ST79, ISO 17665-1,-2, ISO 11737-1,-2, and ISO 11138-1
- Biocompatibility testing for subject Abutments according to ISO 10993-1:2009 referenced in K171027, K171694, and K222913

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

Gamma sterilization test was performed for our other device, Healing Abutment (DSHZ7890C) as test specimen and leveraged for the subject device because material, manufacturing process, sterilization and packaging of both products are exactly same.

The end user sterilization test was performed for the predicate device K171027 and reference 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.
For other subject devices made with other materials as POM, PEEK and Pure Titanium Gr4, the end user sterilization validation reports are provided.

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

Conclusion

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