February 4, 2020

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

Re: K192688
Trade/Device Name: s-Clean SQ-SL Implant System Regular
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 2, 2019
Received: November 12, 2019

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)*
K192688

Device Name
s-Clean SQ-SL Implant System Regular

Indications for Use *(Describe)*
s-Clean SQ-SL Implant System Regular 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.

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Dentis Co., Ltd.
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Tel : 82.53.582.2804 / Fax : 82.53.583.2806

510(K) Summary

Submitter
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Device Information

- Trade Name: s-Clean SQ-SL Implant System Regular
- Common Name: Dental Implant System
- Classification Name: implant, endosseous, root-form
- Product Code: DZE
- Secondary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Date Prepared: 01/28/2020

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

Primary Predicate

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

Reference Predicates

- K171027, Dentis Dental Implant System by Dentis Co., Ltd.
- K171694, s-Clean TiN Coating Abutments by Dentis Co., Ltd.

Indication for Use:
s-Clean SQ-SL Implant System Regular 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 Co., Ltd.
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Device Description:

s-Clean SQ-SL Implant System Regular is composed of Fixture and Abutments. s-Clean SQ-SL Fixture is a thread type implant made of Commercial Pure Titanium Grade 4 according to ASTM F67 which will be placed in the alveolar bone to replace the function of the missing tooth. The device has an internal connection between the implant body and the abutment component.

Fixture's surface is treated with SLA (Sandblasted with Large-grit and Acid-etching).
The implant body is the only part to be implanted into bone (mandibular or maxillary bone), and is to be connected to the abutment.
The dimensions are as following:

Name	Diameter (mm)	Length (mm)
s-Clean SQ-SL Fixture	Ø4.1/Ø4.35/Ø4.8	7.0, 7.5, 9.5, 11.5, 13.5
	Ø5.8/Ø6.8/Ø7.8	7.0, 7.5, 9.5, 11.5

Abutments are composed as below;
s-Clean Sole Abutment S-Line, s-Clean TiN Half Coating Sole Abutment S-Line, and s-Clean Cover Screw.
The dimensions of abutments are as following:

No.	**Device Name**	**Dimensions**	**Angulation**
1	s-Clean Sole Abutment S-Line	Ø4.5, 5.5, and 6.5 mm(D) X 1.8, 2.8 and 3.8mm (Gingival Height) X 4.0mm (Post Height)	0°
2	s-Clean TiN Half Coating Sole Abutment S-Line	Ø4.5, 5.5, and 6.5 mm (D) X 1.8, 2.8 and 3.8mm (Gingival Height) X 4.0mm (Post Height)	0°
3	s-Clean Cover Screw	Ø3.6mm (D) X 5.9mm (L)	0°

The Abutments have below featured:

Name	Uses	Surface	Connection
s-Clean Sole Abutment S-Line	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		TiN-Coating	Internal Hex
s-Clean Cover Screw	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	N/A	Screw Retained

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Materials:

- The s-Clean SQ-SL Fixture and s-Clean Cover Screw are fabricated from Commercial Pure Titanium Grade 4 of ASTM F67
- The s-Clean Sole Abutment S-Line and s-Clean TiN Half Coating Sole Abutment S-Line are fabricated from Ti-6Al-4V ELI of ASTM F136

Summaries of Technology Characteristics:

s-Clean SQ-SL Fixture

	Subject Device	**Primary Predicate Device**
510(k) Number	N/A	K153639
Trade Name	s-Clean SQ-SL Implant System Regular	OneQ-SL s-Clean Implant System
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.
Design (Fixture Type)	 - Internal Hex-connected - Submerged Fixture - Bone level - Tapered body - cutting edge with self-tapping	 - Internal Hex-connected - Submerged Fixture - Bone Level - Tapered & Straight Body - 3 sided cutting edge with self-tapping
Fixture Diameter(Ø)	Regular: 4.1, 4.35, 4.8 Wide: 5.8, 6.8, 7.8	Regular: 3.7,3.9,4.2,4.7,5.2 Wide: 6.0,7.0,8.0
Fixture Length	Regular: 7,7.5,9.5,11.5,13.5mm Wide: 7,7.5,9.5,11.5mm	Regular: 7,8,10,12,14mm Wide: 7,8,10,12mm
Indication for Use	s-Clean SQ-SL Implant System Regular 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.	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.
Surface Treatment	SLA	SLA

Material	CP Titanium Grade 4 (ASTM F67)	CP Titanium Grade 4 (ASTM F67)
Similarities	s-Clean SQ-SL Implant System Regular has similar device characteristics with the Primary predicate devices, OneQ-SL s-Clean Implant System (K153639) such as Length, material, functions, general shape (Design), manufacturing process, and surface treatment are similar. The indications for Use are identical between two devices and that other reference devices used in this submission do not include any component-specific language that would be needed in the subject Indications for Use.	
Differences	The differences are the macro shape of the implant body and small differences in the dimensions proposed; we have provided all descriptive information related to shape and the primary predicate includes the subject device range of dimensions. Therefore, these differences do not impact substantial equivalence.	

s-Clean Sole Abutment S-Line

	Subject Device	**Reference Device**
510(k) Number	N/A	K171027
Trade Name	s-Clean SQ-SL Implant System Regular	Dentis Dental Implant System
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.
Product Name	s-Clean Sole Abutment S-Line	s-Clean Sole Abutment
Design		
Dimension	Ø4.5: 11.6, 12.6, 13.6mm Ø5.5: 11.6, 12.6, 13.6mm Ø6.5: 11.6, 12.6, 13.6mm	Ø4.5: 12.5 – 17mm Ø4.8: 12 – 17mm Ø5.5: 12.5 – 17mm Ø6.0: 13 – 17mm Ø6.5: 12.5 – 17mm
Angulation	N/A	N/A
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Brief Comparison	The general design is similar to the reference device; the differences are minor differences in design and dimensions, though the subject device range of dimensions is included in the reference device. The apparently smaller total length does not impact substantial equivalence as the post height is at least 4mm, which is clinically recommended.	

s-Clean TiN Half Coating Sole Abutment S-Line

	Subject Device	**Reference Device**
510(k) Number	N/A	K171694
Trade Name	s-Clean SQ-SL Implant System Regular	s-Clean TiN Coating Abutments
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.
Product Name	s-Clean TiN Half Coating Sole Abutment S-Line	s-Clean TiN Partial Coating Sole Abutment
Design		
Dimension	Ø4.5: 11.6, 12.6, 13.6mm Ø5.5: 11.6, 12.6, 13.6mm Ø6.5: 11.6, 12.6, 13.6mm	Ø4.5: 8.8 – 13.3mm Ø4.8: 9.3 – 13.3mm Ø5.5: 8.8 – 13.3mm Ø6.0: 9.3 – 13.3mm Ø6.5: 8.8 – 13.3mm
Angulation	N/A	N/A
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Coating	TiN Coating	TiN Coating
Brief Comparison	The general design is similar to the reference device; the differences are minor differences in design and dimensions, though the subject device range of dimensions is included in the reference device. The apparently smaller total length does not impact substantial equivalence as the post height is at least 4mm, which is clinically recommended.	

Substantial Equivalence Discussion

Similarities:

s-Clean SQ-SL Implant System Regular has similar device characteristics with the Primary predicate devices, OneQ-SL s-Clean Implant System (K153639) such as Length, material, functions, general shape (Design), manufacturing process, and surface treatment are similar. The indications for Use are identical between two devices and that other reference devices used in this submission do not include any component-specific language that would be needed in the subject Indications for Use.

Differences:

The differences are the macro shape of the implant body and small differences in the dimensions proposed; we have provided all descriptive information related to shape and the predicates include the subject device range of dimensions. Therefore, these differences do not impact substantial equivalence.

Non-Clinical Test Data

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Bacterial Endotoxin Test Report on Subject Fixture according to ANSI/AAMI ST72:2011, USP <161>, and USP <85>
- Shelf Life Test for subject fixtures according to ASTM F1980

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

- Sterilization Validation Test for subject fixtures according to ISO 11137-1,2,3 referenced in K153639
- Sterilization Validation Test on s-Clean Healing Abutment for subject Cover Screw according to ISO 11137-1,2,3 referenced in K171027
- Shelf Life Test on s-Clean Healing Abutment for subject Cover Screw according to ISO 11137-1,2,3 referenced in K171027
- End User Sterilization Validation Test Report for subject abutments according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1 referenced in K171027
- Biocompatibility testing 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 on fixtures referenced in K153639
- Biocompatibility testing according to ISO 10993-1:2009 on machined surface abutments referenced in K171027.
- Biocompatibility testing according to ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-10:2010, and ISO 10993-11:2006 ISO on s-Clean TiN Coating Abutments in K171694
- Biocompatibility Testing according to ISO 10993-1:2009 on Cover Screw referenced in K171027.

The results of the above tests have met the criteria of the standards, and demonstrated the substantial equivalence with the predicate device. The fatigue testing per ISO 14801 was not conducted as it is not necessary based on the device-specific guidance document
The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion

s-Clean SQ-SL Implant System Regular constitutes a substantially equivalent medical device. This system has the same intended use and fundamental scientific technology as its predicate devices. Any additional small differences do not impact substantial equivalence. Therefore, s-Clean SQ-SL Implant System Regular and its predicates are substantially equivalent.