April 13, 2020

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

Re: K200099
Trade/Device Name: s-Clean SQ-SL Implant System Mini
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: January 10, 2020
Received: January 16, 2020

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 post marketing 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
Implantable Dental Devices Team
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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200099

Device Name
s-Clean SQ-SL Implant System Mini

Indications for Use *(Describe)*
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.

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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Dentis Co., Ltd.

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Tel : 82.53.582.2804 / Fax : 82.53.583.2806

510(K) Summary
K200099

Submitter
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Device Information

- Trade Name: s-Clean SQ-SL Implant System Mini
- 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: 01/08/2020

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

- K161689, OSSTEM Implant System – Abutment by Osstem Implant Co. Ltd
- K171027, Dentis Dental Implant System by Dentis Co., Ltd.
- K171694, s-Clean TiN Coating Abutments

Indication for Use:
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.

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Device Description:

s-Clean SQ-SL Implant System Mini is composed of Fixture and Abutments. s-Clean SQ-SL Implant System 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.
Fixture's surface 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 are as following:

No.	Device Name	Dimension Ranges
1	s-Clean SQ-SL Fixture	Ø 3.7, 4.1mm (D) X 7.0, 7.5, 9.5, 11.5 and 13.5mm (L)

Tolerance of dimension shall be within ± 1% range.

The s-Clean SQ-SL Implant System Mini Abutments are composed as below;
s-Clean Sole Abutment S-Line, s-Clean TiN Half Coating Sole Abutment S-Line, and s-Clean Mini Fixture Cover Screw
The dimensions of abutments are as following:

No.	Device Name	Dimension Ranges	Angulation
1	s-Clean Sole Abutment S-Line	Ø 4.0 and 5.0mm (D) X 11.2, 12.2, 13.2mm (L)	0°
2	s-Clean TiN Half Coating Sole Abutment S-Line	Ø 4.0 and 5.0mm (D) X 11.2, 12.2, 13.2mm (L)	0°
3	s-Clean Mini Fixture Cover Screw	Ø 3.1mm (D) X 5.4mm (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 Mini Fixture 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

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

s-Clean SQ-SL Fixture and s-Clean Mini Fixture Cover Screw are provided sterilized. And the other Abutments are provided non-sterilized.
s-Clean SQ-SL Fixture is enclosed with s-Clean Mini Fixture Cover Screw in a set packing. s-Clean Mini Fixture Cover Screw is also provided separately.

Materials:

- The fixtures and s-Clean Mini Fixture Cover Screw are fabricated from Pure titanium 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 of ASTM F136

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Summaries of Technological 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 Mini	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 - 3 sided 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)	3.7, 4.1mm	3.7, 3.9, 4.2, 4.7, 5.2, 6.0, 7.0, 8.0mm
Fixture Length	7, 7.5, 9.5, 11.5, 13.5mm	7, 8, 9, 10, 12, 14mm
Indication for Use	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.	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 restoration including; cemented retained, screw retained, or overdenture restoration, 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)
Sterilization	Gamma Sterilization	Gamma Sterilization
Product Code	DZE, NHA	DZE
Shelf Life	8 years	8 years
Brief Comparison	s-Clean SQ-SL Implant System Mini has same device characteristics with the Primary predicate devices, OneQ-SL s-Clean Implant System (K153639) such as indications for Use, material, functions, general shape (Design), manufacturing process, dimensions, structure, shelf life and surface treatment. Any differences do not affect the clinical performance and efficacy.	

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s-Clean Sole Abutment S-Line

	Subject Device	**Reference Device**	**Reference Device**
510(k)	N/A	K171027	K161689
Trade Name	s-Clean SQ-SL Implant System Mini	Dentis Dental Implant System s-Clean Sole Abutment	OSSTEM Implant System - Abutment
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.	OSSTEM Implant Co., Ltd.
Product Name	s-Clean Sole Abutment S-Line	s-Clean Sole Abutment	Rigid Abutment
Design			
Dimension	Ø 4.0, 5.0mm (D) X 11.2, 12.2, 13.2mm (L)	Ø 4.5, 4.8, 5.5, 6.0, 6.5mm (D) X 12.5,13.0,13.5,14.,15.0,16.0,17.0mm (L)	Ø 4.0, 4.6, 5.0, 6.0, 7.0mm (D) X 10, 10.4, 11, 11.4, 11.5, 11.9, 12, 12.4, 12.5, 12.9, 13, 13.4, 13.5, 13.9, 14, 14.4, 14.5, 14.9, 15, 15.4, 15.5, 15.9, 16, 16.4, 17, 17.4mm (L)
Angulation	N/A	N/A	N/A
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Titanium Alloy (Ti-6Al-4V)
Sterilization	Steam sterilization by user	Steam sterilization by user	Steam sterilization by user
Product Code	NHA	NHA	NHA
Brief Comparison	The subject device has no difference from the predicate device that affects the clinical performance and efficacy. Dimensional specification of the subject device falls into the range of the reference device.		

s-Clean TiN Half Coating Sole Abutment S-Line

	Subject Device	**Reference Device**	**Reference Device**
510(k)	N/A	K171694	K161689
Trade Name	s-Clean SQ-SL Implant System Mini	s-Clean TiN Coating Abutments	OSSTEM Implant System - Abutment
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.	OSSTEM Implant Co., Ltd.
Product Name	s-Clean TiN Half Coating Sole Abutmebt S-Line	s-Clean TiN Partial Coating Sole Abutment	Rigid Abutment
Design			

Dimension	Ø 4.0, 5.0mm (D) X 11.2, 12.2, 13.2mm (L)	Ø 4.5, 5.5, 6.0 and 6.5mm (D) x 11, 11.5, 12.0, 12.5, 13.5, 14.5, 15.5mm (L)	Ø 4.0, 4.6, 5.0, 6.0, 7.0mm (D) X 10, 10.4, 11, 11.4, 11.5, 11.9, 12, 12.4, 12.5, 12.9, 13, 13.4, 13.5, 13.9, 14, 14.4, 14.5, 14.9, 15, 15.4, 15.5, 15.9, 16, 16.4, 17, 17.4mm (L)
Angulation	N/A	N/A	N/A
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Titanium Alloy (Ti-6Al-4V)
Surface Treatment	TiN Coating	TiN Coating	Non-Coating
Sterilization	Steam sterilization by user	Steam sterilization by user	Steam sterilization by user
Product Code	NHA	NHA	NHA
Brief Comparison	The subject device has no difference from the predicate device that affects the clinical performance and efficacy. Dimensional specification of the subject device falls into the range of the reference device.		

s-Clean Mini Fixture Cover Screw

	Subject Device	**Primary Predicate deviece**
510(k)	N/A	K153639
Trade Name	s-Clean SQ-SL Implant System Mini	OneQ-SL s-Clean Implant System
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.
Design		
Dimension	Ø 3.1mm (D) X 5.4mm (L)	Ø 3.6mm (D) X 5.9mm (L)
Angulation	N/A	N/A
Material	CP Titanium Grade 4 (ASTM F67)	CP Titanium Grade 4 (ASTM F67)
Sterilization	Gamma Sterilization	Gamma Sterilization
Product Code	NHA	NHA
Brief Comparison	The subject device is a bit smaller than the predicate device in its diameter and length. This device (cover screw) is to seal the fixture opening from the exposure to the surrounding tissue during the healing process. Thus, the measurement is not an important factor to the device performance but the fitness accuracy to the fixture opening is. The dimensional difference is ignorable.	

Non-Clinical Test Data

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 K153639
- End User Sterilization Validation Test Report 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 K171027
- 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 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
- 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
- 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 non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion

s-Clean SQ-SL Implant System 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, s-Clean SQ-SL Implant System Mini and its predicates are substantially equivalent.