February 17, 2021

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

Re: K210132
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
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 Part 803) for devices or post-marketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 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 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)*
K210132

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.

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510(k) Summary
K210132

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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
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date Prepared: 01/08/2021

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

Primary Predicate

- K192688, s-Clean SQ-SL Implant System Regular by Dentis Co., Ltd.

Indications 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.

Device Description:
This submission is to add new implants to the previously cleared device, s-Clean SQ-SL Implant System Regular (K192688).
The newly added implant is “s-Clean SQ-SL Fixture with Ø5.2mm diameter”.

The s-Clean SQ-SL Implant System Regular is composed of a fixture and cover screw. The s-Clean SQ-SL Fixture is a thread-type implant made of Commercial Pure Titanium Grade 4 according to ASTM F67

which is placed in the alveolar bone to replace the function of the missing tooth. This device has a connection between the upper prosthesis and the internal Hex.

The Fixture's surface is treated with SLA (Sandblasted with Large-grit and Acid-etching).
It is the only part to be implanted into bone, to provide connection of prosthetic devices or other components of a dental implant set within the human body (mandibular or maxillary bone).
The dimensions are as follows:

Device Name		Diameter (mm)	Length (mm)
s-Clean SQ-SL Fixture		Ø5.2	7.0, 7.5, 9.5, 11.5, 13.5

The fixture is packaged with a cover screw cleared under K192688. The fixture is provided sterile.

Materials:
The Fixture is fabricated from CP Titanium Grade 4 (Conforming to ASTM Standard F67).

Summaries of Technology Characteristics:

1) s-Clean SQ-SL Fixture

	Subject Device	Primary Predicate Device
K number	K210132	K192688
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd
Trade Name	s-Clean SQ-SL Implant Regular System	s-Clean SQ-SL Implant Regular System
Description		
Indications 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.	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.
Diameter (mm)	Ø5.2	Ø4.1, 4.35, 4.8, 5.8, 6.8, 7.8
Length (mm)	7, 7.5, 9.5, 11.5, 13.5	7, 7.5, 9.5, 11.5, 13.5
Surface Treatment	SLA	SLA
Material	CP Titanium Gr. 4 (ASTM F67)	CP Titanium Gr. 4 (ASTM F67)
Sterilization	Gamma irradiation	Gamma irradiation
Shelf Life	8years	8 years

Comparison	The subject device and the primary predicate device have the same characteristics such as Indications for Use, design, length, surface treatment, material, abutment connection, and sterilization method. The difference between the two devices is the diameter. Since the diameter of the subject device is in range of the diameters of the primary predicate, it does not affect product performance. Therefore, the subject device is substantially equivalent.

Non-Clinical Test Data

No new non-clinical testing was performed for the subject device since the subject device compared to the predicate device are substantially equivalent in indications, fundamental technology, material, and design. Any testing provided in the predicate device may be leveraged for the subject device because of using the same materials, manufacturing methods, and sterilization procedures. Although the diameters are slightly different, it does not impact the ability to determine substantial equivalence of the subject device because the diameter of the subject device is within the range of diameters of the primary predicate.

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

- Sterilization Validation Test for subject fixtures according to ISO 11137-1, 2, 3 referenced in K192688
- Shelf Life Test for subject fixtures according to ASTM F1980 referenced in K153639
- 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 referenced in K153639
- Bacterial Endotoxin Test Report for subject 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 surface modification information with SLA (Sandblasted with Large-grit and Acid-etching) was provided. To compare surface modification between the subject and predicate devices, K153639, surface roughness, surface composition analysis, and SEM imaging were provided and it demonstrated substantial equivalence.
The fatigue testing per ISO 14801 was not conducted as the subject device is not compatible with any angled abutments.
Non-clinical tests followed the recommendations in the “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments”.

Conclusion

The s-Clean SQ-SL Implant System Regular 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, the s-Clean SQ-SL Implant System Regular is substantially equivalent.