K202773

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

Re: K202773
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, NHA
Dated: February 10, 2021
Received: February 17, 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 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 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K202773

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(K) Summary

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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: 03/18/2021

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

**Primary Predicate**

- K200099, s-Clean SQ-SL Implant System Mini by Dentis Co., Ltd.

**Reference Device**

- K121995, TS Fixture System by OSSTEM Implant Co., Ltd

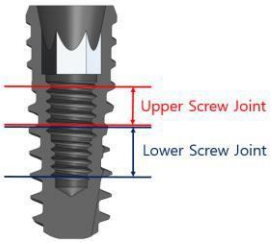
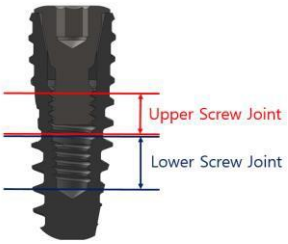
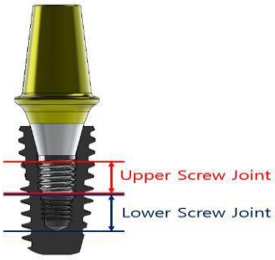
**Indication for Use:**
s-Clean SQ-SL Implant System Mini is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.

**Device Description:**

s-Clean SQ-SL Implant System Mini is composed of Fixture and Abutments. s-Clean SQ-SL Mini Fixture 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.

The s-Clean SQ-SL Implant System Mini Abutments are composed of s-Clean Sole Abutment S-Line, s-Clean TiN Half Coating Sole Abutment S-Line, and s-Clean Mini Fixture Cover Screw.

The subject implant body has a two screw-joint (structured with Upper and Lower screw joints) and a hex anti-rotation design connection. The two-screw-joint feature is for diverse screw connection for 1.6M or 2.0M sizes. The implant bodies are only compatible with subject abutments of S-Clean Sole Abutment s-Line and s-Clean TiN Half Coating Sole Abutment s-Line with 2.0M screw. These abutments are connected with only upper screw of the implant body. The 1.6M size allows the implant to be compatible with potential future cleared abutments.

| Subject Product<br>s-Clean SQ-SL Fixture | Subject Product<br>s-Clean SQ-SL Fixture<br>+<br>s-Clean Cover Screw | Subject Product<br>s-Clean SQ-SL Fixture<br>+<br>s-Clean TiN Half Coating Sole Abutment |
|---|---|---|
|  |  |  |

The surface of fixture 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 of fixtures are as following:

| No. | Device Name | Dimension Ranges |
|---|---|---|
| 1 | s-Clean SQ-SL Mini Fixture | Ø 3.7 and 4.1mm (D) X 7.5, 9.5, 11.5 and 13.5mm (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 Mini Fixture Cover Screw | Ø 3.2mm (D) X 5.0mm (L) | 0° |
| 2 | s-Clean Sole Abutment S-Line | Ø 4.0 and 4.5mm (D) X 11.01, 12.01, 13.01mm (L) | 0° |
| 3 | s-Clean TiN Half Coating Sole Abutment S-Line | Ø 4.0 and 4.5mm (D) X 11.01, 12.01, 13.01mm (L) | 0° |

The Abutments have below featured:

| Name | Uses | Surface | Connection |
|---|---|---|---|
| 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 |
| 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 |

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

s-Clean SQ-SL Mini Fixture and s-Clean Mini Fixture Cover Screw are provided sterilized. And the other Abutments are provided non-sterilized.
s-Clean SQ-SL Mini 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

**Summaries of Technological Characteristics & Substantial Equivalence Discussion:**

**s-Clean SQ-SL Mini Fixture**

| Division | Subject Device | Primary Predicate | Reference Device |
|---|---|---|---|
| 510(k) Number | N/A | K200099 | K121995 |
| Trade Name | s-Clean SQ-SL Implant System Mini | s-Clean SQ-SL Implant System Mini | TS Fixture System |
| Manufacturer | Dentis Co., Ltd | Dentis Co., Ltd | OSSTEM Implant Co., Ltd |
| Product Code | DZE | DZE | DZE |
| Diameter(ø) | 3.7, 4.1 | 3.7, 4.1 | 3.5, 3.75, 3.77, 4.2, 4.25, 4.4, 4.6, 4.63, 4.65, 4.9, 5.05, 5.08, 5.1 |
| Length(mm) | 7.5, 9.5, 11.5, 13.5 | 7, 7.5, 9.5, 11.5, 13.5 | 7.0~15.0 |
| Design |  |  |  |
| Screw-joint | Two screw-joint | One screw-joint | Two screw-joint |
| Surface Treatment | SLA | SLA | SLA |
| Material | CP Titanium Grade4 (ASTM F67) | CP Titanium Grade4 (ASTM F67) | CP Titanium Grade4 (ASTM F67) |
| Abutment Connection Platform | Hex | Hex | Hex |
| Sterilization | Gamma Sterilization | Gamma Sterilization | Gamma Sterilization |
| Shelf-Life | 8years | 8years | 8years |
| 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 TS Fixture System is designed for dental implant surgery; it is placed on the maxillary or mandibular alveolar bone through a surgical procedure, and after osseointegration with the alveolar bone, it can replace a lost tooth by connecting the abutment post. The TS Fixture System is indicated for use in partially or fully dentulous mandibles and maxillae, in support or single or multiple-unit restorations including; cemented retained screw retained or overdenture restorations and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. |
| SE Comparison | The subject device and primary predicate has same characteristics such as indications for Use, outer design, dimensions, surface treatment, material, and sterilization. The difference between two devices is only design of screw joint between fixture and abutment. Subject device has two screw-joint of fixture and abutment but predicate device has only one screw-joint of fixture and abutment. This difference is mitigated through reference device, K121995. Reference device, K121995, has same feature as dual screw joint and screw connection location. Subject device and reference device has dual screw joint and are connected with upper screw joint among upper and low screw joint. Results of dynamic fatigue testing demonstrated that the device is substantially equivalent as the predicates despite the technological differences. | | |

**s-Clean Mini Fixture Cover Screw**

| Division | Subject Device | Primary Predicate Device |
|---|---|---|
| 510(k) Number | N/A | K200099 |
| Trade Name | s-Clean SQ-SL Implant System Mini | s-Clean SQ-SL Implant System Mini |
| Manufacturer | Dentis Co., Ltd | Dentis Co., Ltd |
| Product Code | NHA | NHA |
| Diameter(ø) | 3.2 | 3.1 |
| Length(mm) | 5.0 | 5.4 |
| Material | CP Titanium Grade4 (ASTM F67) | CP Titanium Grade4 (ASTM F67) |
| Sterilization | Gamma Sterilization | Gamma Sterilization |
| Comparison | The subject device and predicate device have same characteristic such as design, material, sterilization, and indication for Use.<br>The diameter and length are slight difference but this difference is not an important factor to the device performance. | |

**s-Clean Sole Abutment S-Line**

| Division | Subject Device | Primary Predicate Device |
|---|---|---|
| 510(k) Number | N/A | K200099 |
| Trade Name | s-Clean SQ-SL Implant System Mini | s-Clean SQ-SL Implant System Mini |
| Manufacturer | Dentis Co., Ltd | Dentis Co., Ltd |
| Product Code | NHA | NHA |
| Diameter(ø) | 4.0, 4.5 | 4.0, 5.0 |
| Length(mm) | 11.01, 12.01, 13.01 | 11.2, 12.2, 13.2 |
| Material | Ti-6Al-4V ELI (ASTM F136) | Ti-6Al-4V ELI (ASTM F136) |
| Angulation | N/A | N/A |
| Sterilization | Steam sterilization by End user | Steam sterilization by End user |
| Comparison | The subject device and predicate device have same characteristic such as design, material, sterilization, angulation and indication for Use.<br>The subject device has shorter lengths of the abutments such as 11.01mm, however, this difference is minimal and does not impact device performance as demonstrated by fatigue testing. In conclusion, subject device and predicate device are substantially equivalent. | |

**s-C lean TiN Half Coating Sole Abutment S-Line**

| Division | Subject Device | Primary Predicate Device |
|---|---|---|
| 510(k) Number | N/A | K200099 |
| Trade Name | s-Clean SQ-SL Implant System Mini | s-Clean SQ-SL Implant System Mini |
| Manufacturer | Dentis Co., Ltd | Dentis Co., Ltd |
| Product Code | NHA | NHA |
| Diameter(ø) | 4.0, 4.5 | 4.0, 5.0 |
| Length(mm) | 11.01, 12.01, 13.01 | 11.2, 12.2, 13.2 |
| Material | Ti-6Al-4V ELI (ASTM F136) | Ti-6Al-4V ELI (ASTM F136) |
| Angulation | N/A | N/A |
| Sterilization | Steam sterilization by End user | Steam sterilization by End user |
| Surface Treatment | TiN Coating | TiN Coating |
| Comparison | The subject device and predicate device have same characteristic such as design, material, sterilization, angulation, surface treatment, and indication for Use.<br>The subject device has shorter lengths of the abutments such as 11.01mm, however, this difference is minimal and does not affect device performance as demonstrated by fatigue testing. In conclusion, subject device and predicate device are substantially equivalent. | |

**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 surface modification information with SLA (Sandblasted with Large-grit and Acid-etching) for fixtures 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 demonstrate the substantial equivalence.
The Sterilization validation test and shelf-life test for fixtures were performed for predicate device, K153639 and leveraged for the subject device because the material, sterilization method, packaging methods, and manufacturing process of the both products are exactly same.
The end user sterilization test was performed for predicate device, K171027 and leveraged for the subject device because the product category, material, manufacturing process, facility, and packaging of the both products are exactly same.
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 fatigue testing per ISO 14801 was conducted under the worst-case scenario. To demonstrate the substantial equivalence of the device performance between single screw joint implant and dual screw joint implant, two fatigue tests were performed comparatively, and result say that device performance was substantial equivalent.

| Fatigue Test Report | Predicate Device | Subject Device-1 | Subject Device-2 |
|---|---|---|---|
| Fixture Size | Ø 3.7 x 13.5mm | Ø 3.7 x 7.5mm | Ø 3.7 x 13.5mm |
| Abutment Size | Ø 4.0 x 12.2mm | Ø 4.5 x 13.01mm | Ø 4.5 x 13.01mm |
| Screw Joint Design | Single | Dual | Dual |
| Compressive Load Result | Similar | Similar | Similar |
| Fatigue Test Method (ISO Standard) | ISO14801:2016 | ISO14801:2016 | ISO14801:2016 |
| Fatigue Test Result (Limit) | Identical | Identical | Identical |
| Gap of connection part | 0 μm | 0 μm | 0 μm |

| | |
|---|---|
| Comparison | Our Subject Devices have dual screw joint feature and this screw connection has difference of screw depth.<br>Our subject devices divide two groups according to screw joint depth and Subject Device-1 and Subject Device-2 are determined as worst case of fatigue test. Two fatigue test result is same, so difference of screw joint depth is not affected to fatigue test. Finally, comparison of fatigue limits between predicate device with single screw joint and subject device with dual screw joint is identical. Predicate device and subject device are substantially equal. |

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.