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

March 4, 2026

Re: K253493
Trade/Device Name: Dentis SQ-SL AXEL Fixture
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: October 24, 2025
Received: February 2, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 postmarketing 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K253493

Device Name

Dentis SQ-SL AXEL Fixture

Indications for Use *(Describe)*

Dentis SQ -SL AXEL Fixture 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 SQ-SL AXEL Fixture
- Common Name: Endosseous dental implant
- Classification Name: implant, endosseous, root-form
- Product Code: DZE
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date Prepared: 03/03/2026

Predicate Devices:

Primary Predicate

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

Reference Device

- K140934, HIOSSEN Implant System by HIOSSEN, Incorporated
- K153639, OneQ-SL s-Clean Implant System by Dentis Co., Ltd.
- K202773, S-Clean SQ-SL Implant System Mini by Dentis Co., Ltd.
- K210080, Dentis s-Clean s-Line Mini by Dentis Co., Ltd.
- K210134, Dentis s-Clean s-Line by Dentis Co., Ltd.

Indication for Use:
Dentis SQ -SL AXEL Fixture 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 SQ-SL AXEL Fixture is two types as Mini and Regular according to the connection. Dentis SQ-SL AXEL 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 surface of fixture is treated with SLA (Sandblasted with Large-grit and Acid-etching).

The dimensions of fixtures are as following:

No.	Device Name	Dimension Ranges
1	SQ-SL AXEL Fixture	Ø4.2, 4.6, 5.0, 5.4, 6.0, 7.0 (D) X 7.0, 7.5, 8.5, 9.5, 11.5, 13.5, 15.5, 17.5mm
2	SQ-SL AXEL Fixture Mini	Ø3.8, 4.2 (D) X 7.5, 8.5, 9.5, 11.5, 13.5, 15.5, 17.5mm

Tolerance of dimension shall be within ± 1% range.

Dentis SQ-SL Fixture is compatible with K192688 and K210134 as below:

510(K)	Abutment Name	Diameter(Ø)	Angulation	Length(mm)
K192688	s-Clean Cover Screw	Ø3.6mm	0	5.9mm
	s-Clean (TiN Half Coating) Sole Abutment S-Line	Ø4.5, 5.5, 6.5 and 7.5	0	11.6, 12.6 and 13.6
K210134	s-Clean (TiN Half Coating) Angled Abutment	Ø4.5	15	12.6

Dentis SQ-SL Fixture Mini is compatible with K210080 as below:

510(K)	Abutment Name	Diameter (Ø)	Angulation	Length(mm)
K210080	s-Clean Cover Screw Mini	Ø3.2mm	0	5.0mm
	s-Clean Healing Abutment S-Line Mini	Ø4.3, 4.8 and 5.8	0	7.61, 8.61, 9.61, 10.61, 11.61, 12.61 and 14.61
	s-Clean (TiN Half Coating) Sole Abutment Mini	Ø4.5 and 5.5	0	11.01, 12.01, 12.51, 13.01, 13.521, 14.01, 14.51, 15.01, 15.51, 16.01 and 17.01
	s-Clean (TiN Half Coating) Couple Abutment Mini	Ø4.0, 4.5 and 5.5	0	8.35, 8.6, 9.35, 9.6, 9.85, 10.1, 10.35, 10.6, 11.1, 11.35, 11.6, 12.1, 12.85, 13.1, 13.35, 13.6, 14.35 and 14.6
	s-Clean (TiN Half Coating) Angled Abutment Mini	Ø4.0 and 4.5	15	12.09, 12.34, 12.51 and 12.76

Dentis SQ-SL AXEL Fixture is provided sterilized.

Dentis SQ-SL AXEL Fixture is packaged with Cover screw that was cleared in FDA as K192688 and K210080.

Materials:

- SQ-SL AXEL Fixture and SQ-SL AXEL Fixture Mini are fabricated from Pure titanium of ASTM F67

Summaries of Technological Characteristics & Substantial Equivalence Discussion

SQ-SL AXEL Fixture

	Subject Device	Primary Predicate	Reference Device
K number	NA	K192688	K140934
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	HIOSSEN Inc.
Trade Name	Dentis SQ-SL AXEL Fixture	s-Clean SQ-SL Implant System Regular	Osstem Implant System
Product Name	SQ-SL AXEL Fixture	s-Clean SQ-SL Fixture	ETII SA Fixture
Design			
Indications for Use	Dentis SQ-SL AXEL Fixture 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 and not dedicated for immediate loading. This system is intended for delayed loading.	The HIOSSEN Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multipleunit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. ETIII SA Ultra-Wide Fixture is intended to be used in the molar region.
Diameter and Length	Regular: Ø4.2 x 7, 7.5, 8.5, 9.5, 11.5, 13.5, 15.5, 17.5mm Ø4.6 x 7, 7.5, 8.5, 9.5, 11.5, 13.5, 15.5, 17.5mm Ø5.0 x 7, 7.5, 8.5, 9.5, 11.5, 13.5, 15.5, 17.5mm Ø5.4 x 7, 7.5, 8.5, 9.5, 11.5, 13.5mm Wide: Ø6.0 x 7, 7.5, 8.5, 9.5, 11.5, mm Ø7.0 x 7, 7.5, 8.5, 9.5, 11.5, mm	Ø4.1 x 7, 7.5, 9.5, 11.5, 13.5mm Ø4.35 x 7, 7.5, 9.5, 11.5, 13.5mm Ø4.8 x 7, 7.5, 9.5, 11.5, 13.5mm Ø5.8 x 7, 7.5, 9.5, 11.5mm Ø6.8 x 7, 7.5, 9.5, 11.5mm Ø7.8 x 7, 7.5, 9.5, 11.5mm	Ø3.5 x 8.7, 10.2,11.7, 13.2, 15.2, 18.2mm Ø4.2 x 7.2, 8.7, 10.2, 11.7, 13.2, 15.2, 18.2mm Ø4.45 x 7.2, 8.7,10.2, 11.7, 13.2, 15.2mm Ø5.0x 6.2mm Ø4.9 x 7.2, 8.7, 10.2, 11.7, 13.2, 15.2mm
Surface Treatment	SLA	SLA	SA
Material	CP Titanium Gr4 (ASTM F67)	CP Titanium Gr4 (ASTM F67)	CP Titanium Gr4 (ASTM F67)
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Shelf Life	8years	8years	8years
Comparison	The Subject Device and primary device, K192688 have same characteristics such as indications for Use, design, surface treatment, material, sterilization, and shelf life. The difference between subject device and primary predicate is dimension. The subject device has longer lengths fixtures, such as 15.5 and 17.5mm. To support this difference, K140934 was added because the dimension combination covers all range of the subject device′s dimensions. Therefore, it is substantially equivalent.		

SQ-SL AXEL Fixture Mini

	Subject Device	Reference Device	Reference Device
K number	NA	K202773	K140934
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd	HIOSSEN Inc.
Trade Name	Dentis SQ-SL AXEL Mini Fixture	s-Clean SQ-SL Implant System Mini	Osstem Implant System
Product Name	SQ-SL AXEL Mini Fixture	s-Clean SQ-SL Mini Fixture	ETII SA Fixture
Design			
Indications for Use	Dentis SQ-SL Mini Fixture 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 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 HIOSSEN Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multipleunit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. ETIII SA Ultra-Wide Fixture is intended to be used in the molar region.
Diameter and Length	Ø3.8 x 7.5, 8.5, 9.5, 11.5, 13.5, 15.5, 17.5mm Ø4.2 x 7.5, 8.5, 9.5, 11.5, 13.5, 15.5, 17.5mm	Ø3.7 x 7.5, 9.5, 11.5, 13.5mm Ø4.1 x 7.5, 9.5, 11.5, 13.5mm	Ø3.5 x 8.7, 10.2, 11.7, 13.2, 15.2, 18.2mm Ø4.2 x 7.2, 8.7, 10.2, 11.7, 13.2, 15.2, 18.2 Ø4.45 x 7.2, 8.7, 10.2, 11.7, 13.2, 15.2mm Ø5.0x 6.2mm Ø4.9 x 7.2, 8.7, 10.2, 11.7, 13.2, 15.2mm
Surface Treatment	SLA	SLA	SA
Material	CP Titanium Gr4 (ASTM F67)	CP Titanium Gr4 (ASTM F67)	CP Titanium Gr4 (ASTM F67)
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Shelf Life	8years	8years	8years
Comparison	The Subject Device and reference device, K202773 have same characteristics such as indications for Use, design (dual screw joint), surface treatment, material, sterilization, and shelf life. The difference between subject device and primary predicate is dimension. The subject device has longer lengths fixtures, such as 15.5 and 17.5mm. To support this difference, K140934 was added because the dimension combination covers all range of the subject device's dimensions. Therefore, it is substantially equivalent.		

Non-Clinical Test Data

Below tests were performed on subject device:

- Fatigue Testing according to ISO 14801:2016 under the worst-case scenario
- SEM/EDS analysis

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 K192688
- 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
- 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.

Non-clinical test data was conducted in accordance with FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments". Clinical testing was not necessary to establish substantial equivalency of the device.

The surface modification information with SLA (Sandblasted with Large-grit and Acid-etching) for fixtures was provided. The implant body surface was characterized using Scanning Electron Microscopy (SEM) and Energy Dispersive X-ray Spectroscopy (EDS).

The Sterilization validation test and shelf-life test for fixtures were performed for cleared device, K192688 and K153639 and leveraged for the subject device because the material, sterilization method, packaging methods, and manufacturing process of both products are exactly same.

The Biocompatibility Test was conducted on the predicate device, K153639 and leveraged for the subject device because both products are manufactured with the same materials and manufacturing process. It demonstrates that the subject device is biocompatible and substantial equivalence with the predicate.

Dynamic fatigue tests were newly performed on the subject device with the compatible abutments to demonstrate the mechanical value according to the FDA guidance document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" and ISO 14801. The Results of fatigue testing showed that subject devices are substantially equivalent under the worst-case scenario.

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

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic. Dentis SQ-SL AXEL Fixture in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry 0., Jana G. Delfino, and Sunder Rajan. 'Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795)., based on the entire system including all variations (all compatible implant bodied, dental abutments and, fixation screws) and material composition. Rationale addressed parameters per the FDA Guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

Conclusion

Dentis SQ-SL AXEL Fixture 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, Dentis SQ-SL AXEL Fixture and its predicates are substantially equivalent.