



May 20, 2024

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

Re: K240511

Trade/Device Name: Dentis s-Clean SQ-SL Fixture  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: Class II  
Product Code: DZE  
Dated: February 21, 2024  
Received: February 22, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

*Sherrill Lathrop Blitzer*

for Andrew Steen  
Assistant Director  
DHT1B: Division of Dental and  
ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT and Dental Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K240511

Device Name

Dentis s-Clean SQ-SL Fixture

Indications for Use (Describe)

Dentis s-Clean SQ-SL 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****Submitter**

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**Device Information**

- Trade Name: Dentis s-Clean SQ-SL Fixture
- Common Name: implant, endosseous, root-form
- Classification Name: Endosseous dental implant
- Product Code: DZE
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date Prepared: 05/16/2024

**Predicate Devices:**Primary and Reference Device

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

Reference Device

- K140934, HIOSSEN Implant System manufactured 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.
- K222778, Osstem Implant System by Osstem Implant Co., Ltd.

**Indications for Use:**

Dentis s-Clean SQ-SL 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 s-Clean SQ-SL Fixture is two type as Mini and Regular according to the connection. Dentis s-Clean SQ-SL 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   | s-Clean SQ-SL Fixture      | Ø4.35, 4.8 and 5.2 (D) X 15.5 and 17.5mm |
| 2   | s-Clean SQ-SL Fixture Mini | Ø3.7 and 4.1 (D) X 15.5 and 17.5         |

Tolerance of dimension shall be within  $\pm 1\%$  range.

s-Clean SQ-SL Fixture is compatible with devices in 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-Clen (TiN Half Coating)<br>Sole Abutment S-Line | Ø4.5, 5.5, 6.5 and 7.5 | 0          | 11.6, 12.6 and 13.6 |
| K210134 | s-Celan (TiN Half Coating)<br>Angled Abutment     | Ø4.5                   | 15         | 12.6                |

s-Clean SQ-SL Fixture Mini is compatible with devices in 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-Celan (TiN Half Coating)<br>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-Celan (TiN Half Coating)<br>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-Celan (TiN Half Coating)<br>Angled Abutment Mini | Ø4.0 and 4.5      | 15         | 12.09, 12.34, 12.51 and 12.76                                                                                    |

Dentis s-Clean SQ-SL Fixture is provided sterilized.

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

**Materials:**

- Dentis s-Clean SQ-SL Fixture is fabricated from Pure titanium of ASTM F67

## Summaries of Technological Characteristics & Substantial Equivalence Discussion

### s-Clean SQ-SL Fixture

|                     | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                | Primary Predicate                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                | Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| K number            | K240511                                                                                                                                                                                                                                                                                                                                                                                                                       | K192688                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | K140934                                                                                                                                                                                                                                                                                                                                                                                                         | K222778                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Manufacturer        | Dentis Co., Ltd                                                                                                                                                                                                                                                                                                                                                                                                               | Dentis Co., Ltd                                                                                                                                                                                                                                                                                                                                                                                                                                                               | HIOSEN Inc.                                                                                                                                                                                                                                                                                                                                                                                                     | Osstem Implant CO., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Trade Name          | Dentis s-Clean SQ-SL Fixture                                                                                                                                                                                                                                                                                                                                                                                                  | s-Clean SQ-SL Implant System Regular                                                                                                                                                                                                                                                                                                                                                                                                                                          | HIOSEN IMPLANT SYSTEM                                                                                                                                                                                                                                                                                                                                                                                           | Osstem Implant System                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Product Name        | s-Clean SQ-SL Fixture                                                                                                                                                                                                                                                                                                                                                                                                         | s-Clean SQ-SL Fixture                                                                                                                                                                                                                                                                                                                                                                                                                                                         | ETII SA Fixture                                                                                                                                                                                                                                                                                                                                                                                                 | TSIV SA Implant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Design              |                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Indications for Use | Dentis s-Clean SQ-SL 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 HIOSEN 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 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. | The Osstem 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide Implant system is intended to be used in the molar region. Products with diameter or less than 3.25mm should be used exclusively for the lateral incisor in the maxilla and a central or lateral incisor in the mandible. |
| Diameter and Length | Ø4.35 x 15.5, 17.5mm<br>Ø4.8 x 15.5, 17.5mm<br>Ø5.2 x 15.5, 17.5mm                                                                                                                                                                                                                                                                                                                                                            | Ø4.1 x 7, 7.5, 9.5, 11.5, 13.5mm<br>Ø4.35 x 7, 7.5, 9.5, 11.5, 13.5mm<br>Ø4.8 x 7, 7.5, 9.5, 11.5, 13.5mm<br>Ø5.8 x 7, 7.5, 9.5, 11.5mm<br>Ø6.8 x 7, 7.5, 9.5, 11.5mm<br>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<br>Ø4.2 x 7.2, 8.7, 10.2, 11.7, 13.2, 15.2, 18.2mm<br>Ø4.45 x 7.2, 8.7, 10.2, 11.7, 13.2, 15.2mm<br>Ø5.0 x 6.2mm<br>Ø4.9 x 7.2, 8.7, 10.2, 11.7, 13.2, 15.2mm                                                                                                                                                                                                        | Ø4.4 x 18mm<br>Ø4.8 x 18mm<br>Ø5.25 x 18mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Surface Treatment   | SLA                                                                                                                                                                                                                                                                                                                                                                                                                           | SLA                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | SA                                                                                                                                                                                                                                                                                                                                                                                                              | SA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Material            | CP Titanium Gr4 (ASTM F67)                                                                                                                                                                                                                                                                                                                                                                                                    | CP Titanium Gr4 (ASTM F67)                                                                                                                                                                                                                                                                                                                                                                                                                                                    | CP Titanium Gr4 (ASTM F67)                                                                                                                                                                                                                                                                                                                                                                                      | CP Titanium Gr4 (ASTM F67)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

|               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                   |                   |                   |
|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|-------------------|
| Sterilization | Gamma Irradiation                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Gamma Irradiation | Gamma Irradiation | Gamma Irradiation |
| Shelf Life    | 8years                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 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 and K222778 were added because the dimension combination of two devices covers all range of the subject device's dimensions. |                   |                   |                   |

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

|                     | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                                   | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| K number            | K240511                                                                                                                                                                                                                                                                                                                                                                                                                       | K202773                                                                                                                                                                                                                                                                                                                                                                                                                            | K140934                                                                                                                                                                                                                                                                                                                                                                                                         |
| Manufacturer        | Dentis Co., Ltd                                                                                                                                                                                                                                                                                                                                                                                                               | Dentis Co., Ltd                                                                                                                                                                                                                                                                                                                                                                                                                    | HIOSEN Inc.                                                                                                                                                                                                                                                                                                                                                                                                     |
| Trade Name          | Dentis s-Clean SQ-SL Fixture                                                                                                                                                                                                                                                                                                                                                                                                  | s-Clean SQ-SL Implant System Mini                                                                                                                                                                                                                                                                                                                                                                                                  | Osstem Implant System                                                                                                                                                                                                                                                                                                                                                                                           |
| Product Name        | s-Clean SQ-SL Mini                                                                                                                                                                                                                                                                                                                                                                                                            | s-Clean SQ-SL Mini Fixture                                                                                                                                                                                                                                                                                                                                                                                                         | ETII SA Fixture                                                                                                                                                                                                                                                                                                                                                                                                 |
| Design              |                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                              |
| Indications for Use | Dentis s-Clean SQ-SL 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 HIOSEN 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 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 | Ø3.7 x 15.5, 17.5mm<br>Ø4.17 x 15.5, 17.5mm                                                                                                                                                                                                                                                                                                                                                                                   | Ø3.7 x 7.5, 9.5, 11.5, 13.5mm<br>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<br>Ø4.2 x 7.2, 8.7, 10.2, 11.7, 13.2, 15.2, 18.2<br>Ø4.45 x 7.2, 8.7, 10.2, 11.7, 13.2, 15.2mm<br>Ø5.0x 6.2mm<br>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 the two devices is dimension. To support this difference, K140934 was added because the dimension combination of K140934 covers all range of the subject device's dimensions.                           |                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                 |

**Non-Clinical Test Data**

Below tests were performed on subject device:

- Fatigue Testing under the worst-case scenario according to ISO 14801:2016

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 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 s-Clean SQ-SL Fixture in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., 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 s-Clean SQ-SL 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 s-Clean SQ-SL Fixture and its predicates are substantially equivalent.