Newton Implant Systems, Inc.
℅ Joyce Kwon
CEO
Provision Consulting Group, Inc.
100 N Barranca St. Suite 700
West Covina, California 91791

January 18, 2024

Re: K221866
Trade/Device Name: S-Plant Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: December 20, 2023
Received: December 21, 2023

Dear Joyce Kwon:

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221866

Device Name
S-Plant Dental Implant System

Indications for Use *(Describe)*

The S-Plant Dental Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The smaller S-Plant Dental Implants (Ø3.4, 3.6, 3.8, 4.2, 4.7, 5.2 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger S-Plant Dental Implants (Ø6.0, 7.0 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.

Dual abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.

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

510(k) Submitter
Aiden Lee
IDIS Co, Ltd.
#1314 ~ #1319, 122, Jomaru-ro, 385 beon gil, Bucheon-si,
Gyeunggi-do, 14556, Republic of Korea

Official Correspondent / Contact Person
Joyce Kwon, CEO/Principal Consultant
Provision Consulting Group, Inc.
13925 City Center Dr. Suite 200
Chino Hills, CA 91709
+1-909-493-3276
joyce@provisionfda.com

Date Prepared: 1/12/2024

Device Information

- Trade Name: S-Plant Dental Implant System
- Common Name: Endosseous Dental Implant
- Classification Name: Endosseous dental implant
- Regulation Number: 21 CFR 872.3640
- Device Class: Class II
- Primary Product Code: DZE
- Secondary Product Code: NHA

Predicate
Devices Fixture:

- DIO UF HSA Internal Sub-merged Implant System (K122519)

Reference Device

Fixture

- DIO UF(II) Narrow Implant System (K161987)

Abutment:

- Angled Abutment- Osstem Implant Angled Abutment (K182091)
- Transfer Abutment- Osstem Implant Transfer Abutment (K182091)
- Healing Abutment- Hiossen Healing Abutment (K203360)

Accessories:

- Cover Screw- Dentium Implantium SuperLine Abutments - Cover Screw (K141457)
- Abutment Screw- Osstem Implant Abutment Screw (K182091)

Prior Submission Information
N/A

Indications for Use

The S-Plant Dental Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The smaller S-Plant Dental Implants (Ø3.4, 3.6, 3.8, 4.2, 4.7, 5.2 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger S-Plant Dental Implants (Ø6.0, 7.0 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.
Dual abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures. Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration. Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and enabling the transition to final restoration components once osseointegration is complete.

Device Description
The S-Plant Dental Implant System is comprised of dental implants, superstructures, instruments for prosthetics and surgical instruments. The S-Plant Dental Implant System is specially designed for use in dental implant surgery. A successfully osseointegrated implant will achieve a firm implant when surgically implanted under controlled conditions. There are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations.

The S-Plant Dental Implant System fixtures are made of commercial pure titanium, grade 4 (ASTM F67) which have a S.L.A (Sand blasted large grit acid etched) treated surface and supplied sterile (gamma radiation). These fixtures can be used one stage surgery method or two stage surgery method. And that are surgically inserted into the upper and/or lower jawbone. The fixtures replace tooth roots providing a stable foundation for restorations.
Geometrically, the implant is screw type. An abutment is connected to the implant through a tapered joint.

The Abutment made of Ti-6AL-4V ELI alloy (ASTM F136) is intended for use as an aid in single or multiple-unit prosthetic restorations. It consists of Healing Abutment, Dual Abutment, and Abutment Screws. All abutments are supplied non-sterile and autoclaved by the end user.

The Cover Screw made of Ti-6Al-4V ELI alloy (ASTM F136), is an essential component in dental implant procedures. This device safeguards the internal threads of dental implant fixtures during the healing phase, ensuring a sterile environment for successful osseointegration.

The dimensions of subject devices are as following:

<table>
<tr><th>No.</th><th>Device Name</th><th>Dimensions</th></tr>
<tr><td>1.</td><td>S-Plant Fixture</td><td>Ø 3.4 x 8.5, 10.0, 11.5, 13.0, 15.0 mm (L)
Ø 3.6 x 8.5, 10.0, 11.5, 13.0, 15.0 mm (L)
Ø 3.8 x 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm (L)
Ø 4.2 x 7.0, 8.5, 10.0, 11.5, 13.0 mm (L)
Ø 4.7 x 7.0, 8.5, 10.0, 11.5, 13.0 mm (L)
Ø 5.2 x 7.0, 8.5, 10.0, 11.5 mm (L)
Ø 6.0 x 7.0, 8.5, 10.0, 11.5 mm (L)
Ø 7.0 x 7.0, 8.5 mm (L)</td></tr>
<tr><td>2.</td><td>Dual Abutment</td><td>
<table>
<tr><th>D(Ø)</th><th>G/H</th><th>Post</th></tr>
<tr><td>4</td><td>1,2,3,4,5</td><td>5.5,7</td></tr>
<tr><td>4.5</td><td>1,2,3,4,5</td><td>5.5,7</td></tr>
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<tr><td>7</td><td>1,2,3,4,5</td><td>5.5</td></tr>
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<tr><td>3.</td><td>Healing Abutment</td><td>Ø 4.0 x 3.0, 4.0, 5.0, 6.0, 7.0 mm (L)
Ø 4.5 x 3.0, 4.0, 5.0, 6.0, 7.0 mm (L)
Ø 5.0 x 3.0, 4.0, 5.0, 6.0, 7.0 mm (L)
Ø 6.0 x 3.0, 4.0, 5.0, 6.0, 7.0 mm (L)
Ø 7.0 x 3.0, 4.0, 5.0, 6.0, 7.0 mm (L)</td></tr>
<tr><td>4.</td><td>Abutment Screw</td><td>Ø 2.25 x 10.2 mm (L)
Ø 2.5 x 9.0 mm (L)</td></tr>
<tr><td>5.</td><td>Cover Screw</td><td>Ø 3.60 x 6.5 mm (L)</td></tr>
</table>

Substantial Equivalent Comparison Chart with Primary Predicate Device and Reference Device for Fixture

	Subject Device	Primary Predicate Device	Reference Device
Product Name	S-Plant Implant System Fixture	DIO UF HSA Internal Sub-merged Implant System	DIO UF(II) Narrow Implant System
510(k) Number	K221866	K122519	K161987
Manufacturer	IDIS	DIO Corporation	DIO Corporation
Classification Regulation	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640
Primary Product Code	DZE	DZE	DZE

Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Indications	The S-Plant Dental Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The smaller S-Plant Dental Implants (Ø3.4, 3.6, 3.8, 4.2, 4.7, 5.2 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger S-Plant Dental Implants (Ø6.0, 7.0 mm) can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.	The DIO UF HSA Internal Sub-Merged Implant Systems indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The smaller The DIO UF HSA Internal Sub-Merged (Ø3.8 ~ Ø5.5) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger (Ø6.0 ~ Ø7.0) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.	The UF(II) Narrow Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols: - The intended use for the 3.0mm, 3.3mm diameter UF(II) Narrow Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. - It is intended for delayed loading.
Prosthetic Interface Connection	Tapered conical hex	Tapered conical hex	Tapered conical hex

Fixture Diameter and Length	Diameters 3.4 mm; 3.6 mm Each in lengths of 8.5, 10.0, 11.5, 13.0, 15.0 mm Diameter 3.8 mm In lengths of 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm Diameters 4.2 mm; 4.7 mm; Each in lengths of 7.0, 8.5, 10.0, 11.5, 13.0 mm Diameter 5.2 mm; 6.0 mm; Each in lengths of 7.0, 8.5, 10.0, 11.5 mm Diameter 7.0 mm in lengths of 7.0, 8.5 mm	Fixture Diameter: 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 Fixture Length: 7.0, 8.5, 10, 11.5, 13.0, 15.0, 16.0 Extra wide (6.0, 6.5, 7.0) implant bodies are only available in lengths from 7mm to 14.5mm	Fixture Diameter: 3.0, 3.3 Fixture Length: 8.5, 10, 11.5, 13.0, 15.0
Implant Material	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)
Implant Endosseous Surface	S.L.A.	S.L.A.	S.L.A.
Implant Placement	Bone Level	Bone Level	Bone Level
Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization

Substantial Equivalence Discussion

1. General Indications:

Both the subject device and the predicate device share similar overarching indications for use. They are both designed for surgical placement in the upper and lower jaw arches, with the primary goal of providing a root form means for prosthetic attachment to restore a patient's chewing function.

2. Implant Sizes and Surgical Procedures:

Both systems offer a range of implant sizes to accommodate various clinical scenarios. The smaller implants of both systems (Ø3.4 ~ Ø5.5 mm) can be placed using a conventional two-stage surgical process, with the option for transmucosal healing. Additionally, both systems provide the flexibility of a single-stage surgical process for immediate loading when there is good primary stability, with appropriate occlusal loading.

3. Molar Region and Delayed Loading:

The larger implants in both systems (Ø6.0 ~ Ø7.0 mm) are specifically indicated for the molar region and involve a conventional two-stage surgical process with an option for transmucosal healing, accompanied by delayed loading. This demonstrates a parallel approach to addressing the unique requirements of the molar region.

Discussion:

The comparisons highlight the substantial equivalence between the S-Plant Dental Implant System and the DIO UF HSA Internal Sub-Merged Implant System. The similarities in their indications for use, implant sizes, and surgical procedures demonstrate that the differences between the two devices are not substantial enough to raise any safety or efficacy concerns.

The minor variations in implant dimensions and specific procedural details are well within the acceptable range for dental implant systems, considering the diverse clinical needs and preferences of practitioners. Both systems provide suitable options for immediate loading and delayed loading based on clinical conditions, indicating flexibility in accommodating various patient cases.

The S-Plant Dental Implant System is similar to the predicate device (K122519) in terms of its design, dimensions, material, surface treatment, intended use, and technological characteristics. The S-Plant Dental Implant System also includes diameters (3.4mm and 3.6mm) that are not covered by the predicate device, but they fall within the range between the diameter of the reference device (K161987) and the diameter of the predicate device. Therefore, upon comparing the subject device with both the predicate and reference devices, there have been no new substantial equivalence concerns identified for the S-Plant Dental Implant System in terms of safety and effectiveness.

Substantial Equivalent Comparison Chart with Reference Device for Cover Screw

	Subject Device	Reference Device
Type	Cover Screw	Cover Screw
Secondary Product Code	NHA	NHA
K Number	K221866	K141457
Manufacturer	IDIS	Dentium Company Limited
Description	Cover Screws are used to protect the internal portion of the implant, preventing soft tissue growth into the implant, facilitating provisional restorations when necessary, and	Cover Screws are used to protect the internal portion of the implant.

	enabling the transition to final restoration components once osseointegration is complete.	
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4V, ASTM F136)
Diameter (mm)	3.6	3.6

Substantial Equivalent Comparison Discussion: Proposed Cover Screw and the predicated cover screw have common in design, function, indications for use, material, and dimensions; therefore, the proposed Cover Screw is substantially equivalent to the predicated cover screw (K141457).

Substantial Equivalent Comparison Chart with Reference Device for Abutments

1. **Dual Abutment**

	Subject Device	Reference Device
Abutment Type	Dual Abutment	Transfer Abutment
Secondary Product Code	NHA	NHA
K Number	K221866	K182091
Manufacturer	IDIS	Osstem Implant Co., Ltd.
Design		
Indications for Use	Dual abutments are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Principle of Operation	Using making for general cement-type prosthesis.	Using making for general cement-type prosthesis.
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4V, ASTM F136)

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<tr><td>7</td><td>6,7</td><td>5.5</td></tr>
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Substantial Equivalent Comparison Discussion: Proposed Dual Abutment and the Reference Device, transfer Abutment have common in design, function, indications for use, material, and dimensions; therefore, the proposed Dual Abutment is substantially equivalent to the predicated Transfer Abutment (K182091).

2. Healing Abutment

	Subject Device	Reference Device
Abutment Type	Healing Abutment	Healing Abutment
Secondary Product Code	NHA	NHA
K Number	K221866	K203360
Manufacturer	IDIS	Hiossen, Inc.
Design		
Indications for Use	Healing abutments are used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration.	Used to make a natural soft tissue shape before setting up prosthetics and removing cover screw after osseointegration.
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Pure Titanium Grade 4 (ASTM F67)
Diameters (mm)	4.0, 4.5, 5.0, 6.0, 7.0	4.0 ~ 8.0
Lengths	3.0 ~ 7.0	3.0 ~ 7.0

Substantial Equivalent Comparison Discussion: Proposed Healing Abutment and the Reference Device Healing Abutment have common in design, function, indications for use, material, and dimensions; therefore, the proposed Healing Abutment is substantially equivalent to the reference device Healing Abutment (K203360).

3. Abutment Screw

	Subject Device	Reference Device
Type	Abutment Screw	Abutment Screw
Secondary Product Code	NHA	NHA
K Number	K221866	K182091
Manufacturer	IDIS	Osstem Implant Co., Ltd.
Description	Abutment Screw is used to connect an abutment to the fixture	Abutment Screw is used to connect an abutment to the fixture
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4V, ASTM F136)
Diameter (mm)	2.25, 2.5	2, 2.05
Length (mm)	9.0, 10.2	7.5, 9.6

Substantial Equivalence Discussion for Abutment Screw
The Proposed Abutment Screw and the reference device Abutment Screw share similar indications for use and material composition. Although the diameter and length of the screws differ slightly, the gap range is minimal, measuring less than 1-1.5mm. Consequently, this variance does not give rise to any concerns about the safety and effectiveness of the Proposed Abutment Screw. To sum up, the Proposed Abutment Screw can be deemed substantially equivalent to the reference device Abutment Screw (K182091).

Non-Clinical Test Data

The subject device was tested to evaluate its performance as below.

- ISO 7405:2018, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing
- ISO 10993-3:2014, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6:2016, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

- ISO 10993-11:2018, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-12:2012, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

The non-clinical test data submitted for the S-Plant Dental Implant System validates its substantial equivalence to the predicate device. The device's safety and effectiveness are ensured through sterilization validation, involving both gamma radiation and gravity displacement moist heat, in addition to shelf-life determination conducted through accelerated aging studies. Surface modification testing, utilizing EDS and SEM evaluations, further confirms the consistency and appropriateness of the S.L.A treated surface.

These non-clinical assessments adhere rigorously to recognized standards, including ISO 11137, ANSI/AAMI ST79, and ASTM F1980, reinforcing the reliability and validity of our data. The outcomes collectively support the substantial equivalence of the S-Plant Dental Implant System to the predicate device.

The results of these comprehensive tests have met the criteria set by industry standards, establishing substantial equivalence with the predicate device. The non-clinical testing procedures followed the guidelines outlined in the FDA document "Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments." The conclusive results of the non-clinical testing clearly demonstrate that the S-Plant Dental Implant System is substantially equivalent to the predicate device.

MR Conditional Labeling:

Non-clinical worst-case MRI review was performed to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (i.e., 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 to include all variations (all compatible implant bodies, dental abutments, and fixation screws) and material compositions. The 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.

Conclusions

The S-Plant Dental Implant System is similar to the predicate device (K122519) in terms of its design, dimensions, material, surface treatment, intended use, and technological characteristics. The S-Plant Dental Implant System also includes diameters (3.4mm and 3.6mm) that are not covered by the predicate device, but they fall within the range between the diameter of the reference device (K161987) and the diameter of the predicate device. Therefore, upon comparing the subject device with both the predicate and reference devices, there have been no new

substantial equivalence concerns identified for the S-Plant Dental Implant System in terms of safety and effectiveness.

Each subject abutment type and screw type is substantially equivalent to its reference device. The documentation submitted in this premarket notification demonstrates the S-Plant Dental Implant System is substantially equivalent to the primary predicate and reference devices.