DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 21, 2016

DENTSPLY International, Inc.
Helen Lewis
Director, Corporate Regulatory Affairs
221 West Philadelphia St., Suite 60
York, Pennsylvania 17401

Re: K160207
Trade/Device Name: ATLANTIS™ ISUS Implant Suprastructures
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 19, 2016
Received: August 22, 2016

Dear Helen Lewis,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160207

Device Name

ATLANTIS ISUS™ Implant Suprastructures

Indications for Use *(Describe)*

ATLANTIS™ ISUS Implant Suprastructures are indicated for attachment to dental implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

ATLANTIS™ ISUS Implant Suprastructures are intended for attachment to a minimum of two (2) implants and are indicated for compatibility with the following implant and abutment systems:

Implants:

Manufacturer	**Name of Implant**	**Size**
Biomet 3i	Certain	3.25, 4/3 – Prevail 3/4/3, 4/3
	Certain	4.0, 5/4 – Prevail 4/5/4. 5/4
	Certain	5.0, XP 4/5 – Prevail 5/6/5, 6/5
	Certain	6.0, XP 5/6
BioHorizons	Internal/Tapered	3.5, 4.5, 5.7
Camlog	Screw-line Implant	3.3
	Screw-line / Root-line Implant	3.8, 4.3, 5.0, 6.0
DENTSPLY Implants	XiVE	S 3.0, S 3.4, S 3.8, S 4.5, S 5.5
	OsseoSpeed™ TX	3.0, 3.5/4.0, 4.5/5.0
	Osseospeed™ Profile TX	4.5/5.0
	Osseospeed™ EV	3.0, 3.6, 4.2, 4.8, 5.4
	Osseospeed™ Profile EV	4.2, 4.8
Keystone Dental	PrimaConnex	SD 3.3/3.5
	PrimaConnex	RD 4.0/4.1
	PrimaConnex	WD 5.0
	Genesis	3.8, 4.5, 5.5/6.5
Nobel Biocare	NobelActive	NP 3.5 – RP 4.3, 5.0
	NobelReplace	NP-3.5 – RP 4.3 – WP 5.0 – 6.0
Straumann	Bone Level	3.3 NC – 4.1, 4.8 NC
	Standard Plus	3.5 NN
	Standard / Standard Plus	4.8 RN – 4.8 WN
Zimmer Dental	Tapered Screw Vent	S-V 3.5/S-V 3.3, 3.7 / S-V 4.5/ S-V 4.5
	Tapered Screw Vent	5.7

Abutments:

Manufacturer	Name of Abutment
Biomet 3i	Low Profile Abutment
DENTSPLY Implants	ATIS Uni Abutment EV
	ATIS UniAbutment 20°, ATIS UniAbutment 45°
	ATIS Angled Abutment EV
	ATIS Angled Abutment 20°
	ANKYLOS Balance Base Narrow D4.2, Balance Base D5.5
	XiVE MP 3.4, MP 3.8, MP 4.5, MP 5.5
	XiVE TG 3.4, TG 3.8, TG 4.5
Nobel Biocare	Multi-Unit Abutment RP
Straumann	Bone Level Multi-Base Angled Abutment
	Bone Level Multi-Base Abutment D3.5, D4.5
	RN Abutment Level, WN Abutment Level
	Screw-Retained Abutment 3.5, 4.6
Zimmer Dental	Tapered Abument

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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SECTION 5. 510(k) SUMMARY

for
ATLANTIS™ ISUS Implant Suprastructures

1. Submitter Information**:**

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60W
York, PA 17401

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343

Date Prepared: September 20, 2016

2. Device Name:

- Proprietary Name: ATLANTIS™ ISUS Implant Suprastructures
- Classification Name: Endosseous dental implant abutment
- CFR Number: 21 CFR 872.3630
- Device Class: Class II
- Product Code: NHA

3. Predicate Device:

The subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Primary Predicate Device:

Predicate Device Name	**510(k)**	**Company Name**
ISUS Implant Suprastructures	K122424	DENTSPLY International, Inc.

Reference Predicate Devices:

Predicate Device Name	**510(k)**	**Company Name**
Astra Tech OsseoSpeed Angled Abutment EV	K121810	DENTSPLY International, Inc. (former: ASTRA TECH AB)
Astra Tech Implants-Dental System	K931767	DENTSPLY International, Inc. (former: ASTRA TECH AB)
Astra Tech Implant System	K101732	DENTSPLY International, Inc. (former: ASTRA TECH AB)
Astra Tech OsseoSpeed Plus	K120414	DENTSPLY International, Inc. (former: ASTRA TECH AB)
Astra Tech OsseoSpeed Profile System	K080156	DENTSPLY International, Inc. (former: ASTRA TECH AB)
Astra Tech OsseoSpeed Profile EV	K130999	DENTSPLY International, Inc.
BioHorizons Tapered Internal Implant System	K071638	BioHorizons Implant Systems, Inc.
Camlog Screw Implant System	K000099	Altatec Biotechnologies

Predicate Device Name	510(k)	Company Name
Camlog Rootform Implant System	K000100	Altatec Biotechnologies
Lifecore PrimaConnex Internal Connection Implant System	K051614	Keystone Dental, Inc. (former: Lifecore Biomedical, Inc.)
Genesis Implant System	K101545	Keystone Dental, Inc.
Straumann Magellan Screw-Retained Abutment System	K133421	Institut Straumann AG

4. Description of Device:

The ATLANTIS™ ISUS Implant Suprastructures include new implant and abutment interfaces of the predicate ISUS Implant Suprastructures, cleared in K122424.

The ATLANTIS™ ISUS Implant Suprastructures are patient-specific restorative devices that are intended to be attached to dental implants or abutments to facilitate prosthetic restoration in the treatment of partially and totally edentulous patients. The design of the subject device is derived from patient dental models and completed by DENTSPLY technicians using computer-assisted design (CAD) according to the clinician's prescription. The final CAD design of the ATLANTIS™ ISUS suprastructures are fabricated using computer-assisted manufacturing (CAM) to produce a customized, patient-specific device.

The subject ATLANTIS™ ISUS Implant Suprastructures are available in the same design types as cleared for the predicate ISUS Implant Suprastructures in K122424:

1. Bar – Intended as a fixed supporting structure for a removable dental prosthesis.
2. Bridge – Intended for direct veneering using dental ceramics or resin composites resulting in a fixed, screw-retained prosthesis.
3. Hybrid – Intended as a fixed denture framework.

Screws are available for all compatible implant and abutments systems to screw the ATLANTIS™ ISUS Implant Suprastructures into the implant or onto the abutment.

In addition to the introduction of the new interfaces of the ATLANTIS™ ISUS Implant Suprastructures, the product reference names of the compatible interfaces are adjusted in the indications for use for the currently marketed ATLANTIS™ ISUS Implant Suprastructures to better reflect the original manufacturer's product description.

5. Indications for Use:

ATLANTIS™ ISUS Implant Suprastructures are indicated for attachment to dental implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.
ATLANTIS™ ISUS Implant Suprastructures are intended for attachment to a minimum of two (2) implants and are indicated for compatibility with the following implant and abutment systems:

Implants:

Manufacturer	**Name of Implant**	**Size**
Biomet 3i	Certain	3.25, 4/3 – Prevail 3/4/3, 4/3
	Certain	4.0, 5/4 – Prevail 4/5/4. 5/4
	Certain	5.0, XP 4/5 – Prevail 5/6/5, 6/5
	Certain	6.0, XP 5/6
BioHorizons	Internal/Tapered	3.5, 4.5, 5.7
Camlog	Screw-line Implant	3.3
	Screw-line / Root-line Implant	3.8, 4.3, 5.0, 6.0
DENTSPLY Implants	XiVE	S 3.0, S 3.4, S 3.8, S 4.5, S 5.5
	OsseoSpeed™ TX	3.0, 3.5/4.0, 4.5/5.0
	Osseospeed™ Profile TX	4.5/5.0
	Osseospeed™ EV	3.0, 3.6, 4.2, 4.8, 5.4
	Osseospeed™ Profile EV	4.2, 4.8
Keystone Dental	PrimaConnex	SD 3.3/3.5
	PrimaConnex	RD 4.0/4.1
	PrimaConnex	WD 5.0
	Genesis	3.8, 4.5, 5.5/6.5
Nobel Biocare	NobelActive	NP 3.5 – RP 4.3, 5.0
	NobelReplace	NP-3.5 – RP 4.3 – WP 5.0 – 6.0
Straumann	Bone Level	3.3 NC – 4.1, 4.8 NC
	Standard Plus	3.5 NN
	Standard / Standard Plus	4.8 RN – 4.8 WN
Zimmer Dental	Tapered Screw Vent	S-V 3.5/S-V 3.3, 3.7 / S-V 4.5/ S-V 4.5
	Tapered Screw Vent	5.7

Abutments:

Manufacturer	**Name of Abutment**
Biomet 3i	Low Profile Abutment
DENTSPLY Implants	ATIS Uni Abutment EV
	ATIS UniAbutment 20°, ATIS UniAbutment 45°
	ATIS Angled Abutment EV
	ATIS Angled Abutment 20°
	ANKYLOS Balance Base Narrow D4.2, Balance Base D5.5
	XiVE MP 3.4, MP 3.8, MP 4.5, MP 5.5
	XiVE TG 3.4, TG 3.8, TG 4.5
Nobel Biocare	Multi-Unit Abutment RP
Straumann	Bone Level Multi-Base Angled Abutment
	Bone Level Multi-Base Abutment D3.5, D4.5
	RN Abutment Level, WN Abutment Level
	Screw-Retained Abutment 3.5, 4.6
Zimmer Dental	Tapered Abument

6. Substantial Equivalence:

Technological Characteristics.

An overview of the similarities and differences between the subject and predicate devices is given in Table 1: *Indications for Use for the proposed and the predicate devices* and Table 2: *Similarities and Differences between the proposed and the predicate devices*

Non-Clinical Performance Data.

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence includes: mechanical design analysis, dimensional analysis and static and dynamic compression-bending testing according to ISO 14801 *Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants*. The new interfaces of the ATLANTIS™ ISUS Implant Suprastructures are determined to have sufficient strength for their intended use. Compatibility analysis shows that the subject ATLANTIS™ ISUS Implant Suprastructures are compatible with the predicate implant and abutment systems.

The material used for the ATLANTIS™ ISUS Implant Suprastructures, including the corresponding screws, and the manufacturing process remained unchanged compared to the predicate device, ISUS Implant Suprastructures (K122424). The results of biocompatibility testing conducted for the primary predicate device, ISUS Implant Suprastructures (K122424), are therefore valid and no additional biocompatibility testing has been performed.

No clinical performance data were submitted.

Conclusion Regarding Substantial Equivalence

The ATLANTIS™ ISUS Implant Suprastructures are patient-specific restorative devices that are intended to be attached to dental implants or abutments to facilitate prosthetic restoration in the treatment of partially and totally edentulous patients. The ATLANTIS™ ISUS Implant Suprastructures have the same intended use, composed of the same or similar materials and incorporates the same fundamental technology as the predicate devices, K122424, K121810, K931767, K101732, K120414, K080156, K130999, K071638, K000099, K000100, K051614, K101545, K133421.

Thus, it can be concluded that the subject ATLANTIS™ ISUS Implant Suprastructures are substantially equivalent to the predicate devices.

Table 1: Indications for Use for the proposed and the predicate devices

Subject Device	Indications for Use
DENTSPLY International, Inc. ATLANTIS™ ISUS Implant Suprastructures K122424	ATLANTIS™ ISUS Implant Suprastructures are indicated for attachment to dental implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function. ATLANTIS™ ISUS Implant Suprastructures are intended for attachment to a minimum of two (2) implants and are indicated for compatibility with the following implant and abutment systems: **Implants:** Biomet 3i Certain 3.25, 4/3 - Prevail 3/4/3, 4/3 Biomet 3i Certain 4.0, 5/4 - Prevail 4/5/4, 5/4 Biomet 3i Certain 5.0,XP4/5 - Prevail 5/6/5, 6/5 Biomet 3i Certain 6.0, XP 5/6 BioHorizons Internal/Tapered 3.5, 4.5, 5.7 Camlog Screw-line Implant 3.3 Camlog Screw-line / Root-line Implant 3.8, 4.3, 5.0, 6.0 DENTSPLY Implants XiVE S 3.0, S 3.4, S 3.8, S 4.5, S 5.5 DENTSPLY Implants OsseoSpeed™ TX 3.0, 3.5/4.0, 4.5/5.0 DENTSPLY Implants OsseoSpeed™ Profile TX 4.5/5.0 DENTSPLY Implants OsseoSpeed™ EV 3.0, 3.6, 4.2, 4.8, 5,4 DENTSPLY Implants OsseoSpeed™ Profile EV 4.2, 4.8 Keystone Dental PrimaConnex SD 3.3/3.5 Keystone Dental PrimaConnex RD 4.0/4.1 Keystone Dental PrimaConnex WD 5.0 Keystone Dental Genesis 3.8, 4.5, 5.5/6.5 Nobel Biocare NobelActive NP 3.5 - RP 4.3, 5.0 Nobel Biocare NobelReplace NP 3.5 - RP 4.3 - WP 5.0 - 6.0 Straumann Bone Level 3.3 NC - 4.1, 4.8 RC Straumann Standard Plus 3.5 NN Straumann Standard/Standard Plus 4.8 RN - 4.8 WN Zimmer Dental Tapered S-V 3.5/ S-V 3.3, 3.7 / S-V 4.5/ S-V 4.5 Zimmer Dental Tapered Screw-Vent 5.7

	Abutments: Biomet 3i Low Profile Abutment DENTSPLY Implants ATIS Uni Abutment EV DENTSPLY Implants ATIS UniAbutment 20°, ATIS UniAbutment 45° DENTSPLY Implants ATIS Angled Abutment EV DENTSPLY Implants ATIS Angled Abutment 20° DENTSPLY Implants ANKYLOS Balance Base Narrow D4.2, Balance Base D5.5 DENTSPLY Implants XiVE MP 3.4, MP 3.8, MP 4.5, MP 5.5 DENTSPLY Implants XiVE TG 3.4, TG 3.8, TG 4.5 Nobel Biocare Multi-Unit Abutment RP Straumann Bone Level Multi-Base Angled Abutment Straumann Bone Level Multi-Base Abutment D3.5, D4.5 Straumann RN Abutment Level, WN Abutment Level Straumann Screw-Retained Abutment 3.5, 4.6 Zimmer Dental Tapered Abutment
DENTSPLY International, Inc. ISUS Implant Suprastructures K122424	The ISUS Implant Suprastructures are indicated for attachment to dental implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function. The ISUS Implant Suprastructures are intended for attachment to a minimum of two (2) implants. ISUS Implant Suprastructures are indicated for compatibility with the following implant and abutment systems: Implants: * Nobel Biocare Replace Select: NP (3.5mm), RP (4.3mm), WP (5.0mm), and Replace Select 6.0mm * Nobel Biocare Active Internal: NP (3.5mm), RP (4.3mm, 5.0mm) *Zimmer Screw Vent: 1D3.5, D4.5, D5.7 *Straumann: NN (3.5mm), RN (4.8mm), WN (6.0mm) *Straumann Bone Level: NC (3.3mm), RC (4.1 mm, 4.8mm) *31 Internal Connection: D3.4, D4.1, D5, D6 *Friadent XiVE S: D3, D3.4, D3.8, D4.5, D5.5 Abutments: *Astra Tech- 20° and 45° UniAbutment *Astra Tech UniAbutment EV: 3.6 *ANKYLOS Balance Base Abutment D5.5 and Narrow Abutment D4.2 *Nobel Biocare Multi -Unit Abutment RP: 4.0 mm *Zimmer Tapered Abutment: 4.5mm *Straumann RN(4.8mm), WN (6.5 mm) *Straumann Bone Level: Multi-Base Abutment D3.5, D4.5

	*Straumann Bone Level Angled Abutment:4.0 mm *31 Low Profile Abutment *Friadent XiVE MP D3.8, D4.5, D5.5 *Friadent XiVE TG D3.8, D4.5, D5.5
DENTSPLY International, Inc. Astra Tech OsseoSpeed Angled Abutment EV K121810	OsseoSpeed[Tm] Angled Abutment EV is intended to be used in conjunction with Astra TechImplant System BY in fully edentulous or partially edentulous maxillary and/ar mandibular arches to provide support for bridges or overdentures. The Atlantis[Tm] Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Atlantis [Tm] Crown Abutment in Zircania is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in -partially or completely edentulous patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant. Atlantis [Tm] Abutment and Atlanis [Tm] Crown Abutment are compatible with 05.4 Astra Tech Implant System EV.
DENTSPLY International, Inc. Astra Tech Implants-Dental System K931767	Astra Tech Implant System Angled Abutment 20° is indicated when there is a marked inclination of the fixture in the bucco lingual direction. The use of angled abutment prevents from a situation of penetrating the buccal veneer of the crown when setting the bridge.
DENTSPLY International, Inc. Astra Tech Implant System K101732	The OsseoSpeed™ implants are intended to be used: • to replace missing teeth in single or multiple unit applications within the mandible or maxilla • for immediate placement in extraction sites and partially or completely healed alveolar ridge situations • for both one- and two-stage surgical procedures • especially well in soft bone applications where implants with other implant surface treatments may be less effective • together with immediate loading protocol in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate • together with immediate loading protocol for single-tooth restorations on implants 8 mm or longer • with its 3.0 S product line for maxillary lateral incisors and mandibular lateral and central incisors.
DENTSPLY International, Inc. Astra Tech OsseoSpeed Plus	The OsseoSpeed™ EV implants are intended to be used for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing single and multiple missing teeth in the mandible and maxilla, • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, • especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective,

K120414	• immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. The intended use for OsseoSpeedTM Plus 3.05 is limited to replacement of maxillary lateral incisors and mandibular incisors.
DENTSPLY International, Inc. Astra Tech OsseoSpeed Profile System K080156	OsseoSpeed TX Profile is intended to be used to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. The device may be used equally well in a single-stage or two-stage surgical procedure. It is indicated for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.
DENTSPLY International, Inc. Astra Tech OsseoSpeed Profile EV K130999	OsseoSpeed Profile EV implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing missing teeth in single or multiple unit applications in the mandible or maxilla. • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge • especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective • immediate and early loading for all indications • together with immediate loading protocol in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate
BioHorizons Implant Systems,Inc. BioHorizons Tapered Internal Implant System K071638	The BioHorizons Tapered Internal Implant System is intended for use in the mandible or maxilla for use as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The BioHorizons Tapered Internal Implant System may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion or 2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants.

Altatec Biotechnologies Camlog Screw Implant System K000099	Camlog Screw-Line Implant is intended for endosseous use in the maxilla and mandible for functional aesthetic rehabilitation in partial or fully edentulous patients.Immediate and delayed implantation, as well as immediate or delayed loading.
Altatec Biotechnologies Camlog Rootform Implant System K000100	Camlog Root-Line implants are indicated for single tooth replacement, as immediate abutments on long span to bridge work, as distal abutments on free-end edentulous areas to be restored with fixed bridgework, to support overdentures in totally or partially edentulous arches, and as abutments supporting a full arch fixed prosthesis on the totally edentulous mandible or maxilla.
Keystone Dental, Inc. Lifecore PrimaConnex Internal Connection Implant System K051614	Lifecore Biomedical Dental Implant System implants are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including: cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The PrimaConnexr Internal Connection Implant is a threaded implant that is intended for immediate placement and can be restored with a temporary prosthesis in single tooth and multiple tooth applications with good quality bone. The PrimaConnex Internal Connection Implant is intended for immediate provisionalization,non-occlusal load. Immediate Provisionalization is defined by the International Congress of Oral Implantologists (ICOI) as a clinical protocol for the placement of an interim prosthesis with or without occlusal contact with the opposing dentition, at the same clinical visit of implant placement. The PrimaConnex Internal Connection Implant can be restored with a temporary prosthesis in single tooth and multiple tooth applications with good quality bone.
Keystone Dental, Inc. Genesis Implant System K101545	The Genesis Implant System is intended for use in single-stage or two-stage surgical procedures in all types of bone in partially or fully edentulous mandibles and maxillae. The Genesis Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis implants are intended for placement following natural tooth loss or for immediate placement into an extraction socket. Immediate function may be achieved when good primary stability is established and appropriate occlusal loading is applied.
Institut Straumann AG Straumann Magellan Screw-Retained Abutment System K133421	The Straumann Magellan abutments are indicated to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns, bridges and bars.The final processed devices have the purpose of restoring chewing function. Magellan abutments are indicated for screw-retained restorations.

Table 2: Similarities and Differences between the proposed and the predicate devices

	Subject Device	**Predicate Devices**												
	DENTSPLY International, Inc Atlantis™ ISUS Implant Suprastructures	DENTSPLY International, Inc. ISUS Implant Suprastructures K122424	DENTSPLY International, Inc. Astra Tech OsseoSpeed Angled Abutment EV K121810	DENTSPLY International, Inc. Astra Tech Implants Dental System K931767	DENTSPLY International, Inc. Astra Tech Implants System K101732	DENTSPLY International, Inc. Astra Tech OsseoSpeed Plus K120414	DENTSPLY International, Inc. Astra Tech OsseoSpeed Profile System K080156	DENTSPLY International, Inc. Astra Tech OsseoSpeed Profile EV K130999	BioHorizons Implant Systems, Inc. BioHorizons Tapered Internal Implant System K071638	Altatec Biotechno-logies Camlog Screw Implant System K000099	Altatec Biotechnolo-gies Camlog Rootform Implant System K000100	Keystone Dental, Inc. Keystone Dental Prima Connex Implants K051614	Keystone Dental, Inc. Genesis Implant System K101545	Institut Straumann AG Straumann Magellan Screw-Retained Abutment System K133421
Design														
Prosthesis Attachment	Screw-retained	Screw-retained	Screw-retained	Screw-retained	Screw & Cement-retained	Screw & Cement-retained	Screw & Cement-retained	Screw & Cement-retained	Screw & Cement-retained	Screw & Cement-retained	Screw & Cement-retained	Screw & Cement-retained	Screw & Cement-retained	Screw-retained
Restoration	Multi-unit	Multi-unit	Multi-unit	Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit
Platform Diameter	3.0 - 6.5	3.0 - 6.5	3.6, 4.2, 4.8,5.4	3.5/4.0, 4.5/5.0	3.0, 3.5/4.0 4.5/5.0, 5,0S	3.0, 3.5, 4.0, 4.5, 5.0	4.5/5.0	4.2, 4.8	3.5, 4.5, 5.7	3.3, 3.8, 4.3, 5.0, 6.0	3.3, 3.8, 4.3, 5.0, 6.0	3.5, 4.1, 5.0	3.8,4.5,5.5, 6.5	3.5, 4.6
Connection suprastructure -implant/ abutment	Internal, External	Internal, External	External	External	Internal	Internal	Internal	Internal	Internal	Internal	Internal	Internal	Internal	External
Material														
Abutment	CPTi, CoCr	CPTi, CoCr,	Ti-6Al-4V ELI	Ti-6Al-4V ELI	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6A1-7Nb
Screw	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6A1-7Nb