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

March 31, 2017

Dentsply Sirona
Karl Nittinger
Senior Manager, Corporate Regulatory Affairs
221 West Philadelphia Street
Suite 60
York, Pennsylvania 17404

Re: K163350
Trade/Device Name: Multibase Abutments EV and ATLANTIS Suprastructures
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 24, 2017
Received: February 27, 2017

Dear Karl Nittinger:

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,

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

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)*

Device Name

Multibase Abutments EV

Indications for Use *(Describe)*

The Multibase Abutments EV are intended to be used in conjunction with Astra Tech Implant System EV in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for bridges or overdentures.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

Device Name

ATLANTIS™ Suprastructures

Indications for Use *(Describe)*

ATLANTIS™ 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™ 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/ Screw Vent	Tapered S-V 3.5/S-V 3.3, 3.7 /Tapered S-V 4.5/ S-V 4.5
	Tapered Screw Vent	5.7

Abutments:

Manufacturer	Name of Abutment
Biomet 3i	Low Profile Abutment
DENTSPLY	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
	ATIS Multibase Abutment EV
	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 Abutment

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

SECTION 5. 510(k) SUMMARY
for
Multibase Abutments EV and ATLANTIS™ Suprastructures

1. Submitter Information**:**

Dentsply Sirona
221 West Philadelphia Street
Suite 60
York, PA 17404

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
Fax Number: 717-849-4343

Date Prepared: 30 March 2017

2. Device Name:

- Proprietary Name: Multibase Abutments EV and ATLANTIS™ Suprastructures
- Classification Name: Endosseous dental implant abutment
- CFR Number: 21 CFR 872.3630
- Device Class: Class II
- Product Code: NHA

3. Predicate Device:

The predicate devices for the Multibase Abutments EV and ATLANTIS™ Suprastructures, subject to this bundled 510(k) submission, are as follows:

Predicate devices for the proposed Multibase Abutments EV:

Predicate Device Name	**510(k)**	**Company Name**
OsseoSpeed™ Angled Abutment EV (Primary Predicate Device)	K121810	Dentsply Sirona (formerly ASTRA TECH)
NobelActive Multi Unit Abutment (Reference Predicate Device)	K072570	Nobel Biocare
OsseoSpeed™ Plus (Reference Predicate Device)	K120414	Dentsply Sirona (formerly Astra Tech AB)
OsseoSpeed™ Profile EV (Reference Predicate Device)	K130999	Dentsply Sirona

Predicate device for the modifications relating to the proposed compatibility of the ATLANTIS™ Suprastructures with the proposed Multibase Abutments EV:

Predicate Device Name	**510(k)**	**Company Name**
ATLANTIS™ ISUS Implant Suprastructures (Primary Predicate Device)	K160207	Dentsply Sirona

4. Description of Device:

The subject of this bundled 510(k) consists of the proposed Multibase Abutments EV with accompanying accessories and the corresponding ATLANTIS™ Suprastructures, which are currently marketed under premarket notification K160207 and are proposed for modification under this submission to include compatibility with the proposed Multibase Abutments EV. The proposed devices are intended to be used by dental clinicians for prosthetic restoration in the maxilla and mandible.

The subject Multibase Abutments EV are additional components for the existing OsseoSpeed™ EV implants (cleared in K120414 under the name OsseoSpeed™ Plus) and the OsseoSpeed™ Profile EV implants (K130999). The subject Multibase Abutments EV are designed for multi-unit, screw-retained restorations in a partially or fully edentulous situation. They are provided in three platform diameters (3.6, 4.2 and 4.8 mm) and available as straight version and in two angles (17° and 30°). The straight abutments are one-piece abutments and provided in three gingival heights (1.5, 2.5 and 3.5 mm). They have a non-indexed interface. All abutments with a 17° or 30° angle represent two-piece abutments and are available in two gingival heights (1.5 and 2.5 mm) with an indexed or non-indexed interface. The two-piece, angled variants of the Multibase Abutment EV devices consist of the abutment body and a screw channel cap which is threaded to the abutment body to cover the abutment body's connection screw channel. The screw channel cap features internal threads to facilitate connection of screw-retained restorations. The subject Multibase Abutment EV devices are also designed for compatibility with the temporary prosthetic cylinder and bridge screw components of the reference predicate NobelActive Multi-Unit Abutment system (K072570).

The ATLANTIS™ 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 proposed device is derived from patient dental models and completed by Dentsply Sirona technicians using computer-assisted design (CAD) according to the clinician's prescription. The final CAD design of the ATLANTIS™ Suprastructures are fabricated using computer-assisted manufacturing (CAM) to produce a customized, patient-specific device. The proposed abutment-interface of the ATLANTIS™ Suprastructures, compatible with the proposed Multibase Abutments EV, are available in the same design types as cleared for the predicate ATLANTIS™ ISUS Implant Suprastructures in K160207:

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.
4. 2 in 1 – Intended as a fixed supporting structure for a removable dental prosthesis in combination with a hybrid denture framework retained by friction fit. The primary structure is a non-standard bar configuration. The secondary structure is a bridge or hybrid denture restoration with a tapered friction fit connection rather than a screw-retained connection.

   Screws are available for all compatible implant and abutments systems to attach the ATLANTIS™ Suprastructures to the implant or onto the abutment.

5. Indications for Use:

Multibase Abutments EV

The Multibase Abutments EV are intended to be used in conjunction with Astra Tech Implant System EV in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for bridges or overdentures.

ATLANTIS™ Suprastructures

ATLANTIS™ 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™ 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/ Screw Vent	Tapered S-V 3.5/S-V 3.3, 3.7 /Tapered S-V 4.5/ S-V 4.5
	Tapered Screw Vent	5.7

Abutments:

Manufacturer	Name of Abutment
Biomet 3i	Low Profile Abutment
DENTSPLY	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
	ATIS Multibase Abutment EV
	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 Abutment

6. Substantial Equivalence:

Technological Characteristics

An overview of the similarities and differences between the subject and predicate devices is given in Table 1/ Table 3: *Indications for Use for the proposed and the predicate Abutments/ Suprastructures* and in Table 2/ Table 4: *Similarities and Differences between the proposed and the predicate Abutments/ Suprastructures*

Biocompatibility

The material used for the Multibase Abutments EV and the ATLANTIS™ Suprastructures, including the corresponding screws, and the manufacturing process remained unchanged compared to the corresponding primary predicate devices, OsseoSpeed™ Angled Abutment EV (K121810) and ATLANTIS™ ISUS Implant Suprastructures (K160207). Therefore, no additional biocompatibility testing has been performed.

7. Non-Clinical Performance Data

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence includes:

- Sterilization: Sterilization validation of the sterile, straight variants of the subject Multibase Abutments EV is referenced by equivalence to sterilization validation of existing worst-case challenge validations conducted according to ISO 11137-1 and ISO 11137-2 which conclude that a sterility assurance level (SAL) of 10^{-6} is achieved under the sterilization process parameters utilized. Sterilization validation of the angled variants of the subject Multibase Abutments EV was conducted to validate an SAL of 10^{-6} according to ISO 11137-1 and ISO 11137-2 and the results are summarized in this premarket notification.
- Moist heat sterilization parameters of non-sterile components included with the subject Multibase Abutments EV were validated by equivalence to sterilization validation of existing worst-case challenge validations conducted according to ISO 17665-1 and ISO17665-2 demonstrating a sterility assurance level (SAL) of 10^{-6}.

- Packaging and shelf life validation according to ISO 11607 and ASTM F1980 were conducted and the results are referenced to support substantial equivalence.
- Fatigue Testing: Dynamic fatigue testing conducted on the worst case construct of the subject Multibase Abutments EV devices according to ISO 14801 is included to support substantial equivalence.
- Geometric measurement data and statistical compatibility analysis is included to support the compatibility of the subject Multibase Abutments EV devices with the temporary prosthetic cylinder and bridge screw components of the reference predicate system (K072570).
- Cross-sectional material analysis of the ATLANTIS™ Suprastructures interface with the subject Multibase Abutments EV devices is included and compared to existing worst case interface geometry to support substantial equivalence.

8. Conclusion Regarding Substantial Equivalence

The proposed Multibase Abutments EV and the proposed abutment-interface of the ATLANTIS™ Suprastructures, subject of this bundled 510(k), are endosseous dental implant abutments which are intended to be used by dental clinicians for prosthetic restoration in the maxilla and mandible. The proposed Multibase Abutments EV and the proposed corresponding ATLANTIS™ Suprastructures have the same intended use, incorporates the same fundamental technology, and have similar indications for use as the predicate devices for the Multibase Abutments EV (K121810, K072750, K120414, K130999) and the predicate device for the ATLANTIS™ Suprastructures (K160207), respectively.

Thus, it can be concluded that the proposed Multibase Abutments EV and ATLANTIS™ Suprastructures are substantially equivalent to the predicate devices.

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

Proposed Device	Primary Predicate Device	Reference Predicate Device
Dentsply Sirona Multibase Abutments EV	Dentsply Sirona OsseoSpeed™ Angled Abutment EV K121810	Nobel Biocare NobelActive Multi Unit Abutment K072570
The Multibase Abutments EV are intended to be used in conjunction with Astra Tech Implant System EV in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for bridges or overdentures.	**OsseoSpeed™ Angled Abutment EV is intended to be used in conjunction with Astra Tech implant System EV in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for bridges or overdentures.** The Atlantis™ 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™ Crown Abutment in Zirconia 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™ Abutment and Atlantis™ Crown Abutment are compatible with Ø5.4 Astra Tech Implant System EV.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid prosthetic rehabilitation.

The indications for use of the subject Multibase Abutments EV devices are identical to the cleared indications for use of the primary predicate Osseospeed™ Angled Abutment EV devices cleared in premarket notification K121810. Also cleared in K121810 with the primary predicate Osseospeed™ Angled Abutment EV were the Atlantis™ Abutment and the Atlantis™ Crown Abutment in Zirconia. The Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia were cleared in K121810 with indications for use which are independent from the cleared indications for use of the primary predicate Osseospeed™ Angled Abutment EV (K121810) as shown in Table 1 above. Comparison to the Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia was not included to support the substantial equivalence of the subject Multibase Abutments EV devices.

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

	Proposed Device	**Primary Predicate Device**	**Reference Predicate Device**
	Dentsply Sirona Multibase Abutments EV	Dentsply Sirona OsseoSpeed™ Angled Abutment EV K121810	Nobel Biocare NobelActive Multi Unit Abutment K072570
Design			
Prosthesis Attachment	Screw-retained	Screw-retained	Screw-retained
Restoration	Multi-unit	Multi-unit	Multi-unit
Abutment design	One-piece (0°), Two-piece (17°, 30°)	One-piece	One-piece
Abutment Angulation	0°, 17°, 30°	20°, 30°	0°, 17°, 30°
Gingiva Height	1.5, 2.5, 3.5 mm	1.0, 2.0, 3.0 mm	1.5, 2.5, 3.5, 4.5 mm
Interface abutment-implant	Internal	Internal	Internal
Material			
Abutment	Ti-6Al-4V	Ti-6Al-4V	Ti6Al4V
Screw	Ti-6Al-4V	Ti-6Al-4V	Ti6Al4V
Delivery	sterile	sterile	sterile

The "two-piece" abutment design of the subject angled Multibase Abutments EV devices refers to the threaded superior cap which facilitates the closure of the abutment body's attachment screw channel. When the cap is assembled to the subject angled Multibase Abutments EV abutment body, the superior portion of the abutment device is geometrically identical to that of the one-piece "straight" (0°) abutment design.

Dynamic fatigue testing conducted according to ISO 14801 and referenced in Section 7 of this 510(k) Summary was conducted on the worst case (angled) construct of the subject Multibase Abutments EV devices, which included the two-piece assembly with attached screw channel cap as described above. The results of the dynamic fatigue testing conducted according to ISO 14801 and included in this premarket notification support the substantial equivalence of the subject Multibase Abutments EV.

Table 3: Indications for Use for the proposed and the predicate Suprastructures

Proposed Device			**Predicate Device**		
Dentsply Sirona ATLANTIS™ Suprastructures			Dentsply Sirona ATLANTIS™ Implant Suprastructures K160207		
ATLANTIS™ 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™ Suprastructures are intended for attachment to a minimum of two (2) implants and are indicated for compatibility with the following implant and abutment systems:			ATLANTIS™ 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™ 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:			**Implants:**		
Manufacturer	Name of Implant	Size	Manufacturer	Name of Implant	Size
Biomet 3i	Certain	3.25, 4/3 – Prevail 3/4/3, 4/3	Biomet 3i	Certain	3.25, 4/3 – Prevail ¾/3, 4/3
	Certain	4.0, 5/4 – Prevail 4/5/4. 5/4		Certain	4.0, 5/4 – Prevail 4/5/4. 5/4
	Certain	5.0, XP 4/5 – Prevail 5/6/5, 6/5		Certain	5.0, XP 4/5 – Prevail 5/6/5, 6/5
	Certain	6.0, XP 5/6		Certain	6.0, XP 5/6
BioHorizons	Internal/Tapered	3.5, 4.5, 5.7	BioHorizons	Internal/Tapered	3.5, 4.5, 5.7
Camlog	Screw-line Implant	3.3	Camlog	Screw-line Implant	3.3
	Screw-line / Root-line	3.8, 4.3, 5.0, 6.0		Screw-line / Root-line	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	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™ TX	3.0, 3.5/4.0, 4.5/5.0
	OsseoSpeed™ Profile TX	4.5/5.0		OsseoSpeed™ Profile TX	4.5/5.0
	OsseoSpeed™ EV	3.0, 3.6, 4.2, 4.8, 5.4		OsseoSpeed™ EV	3.0, 3.6, 4.2, 4.8, 5.4
	OsseoSpeed™ Profile EV	4.2, 4.8		OsseoSpeed™ Profile EV	4.2, 4.8
Keystone Dental	PrimaConnex	SD 3.3/3.5	Keystone Dental	PrimaConnex	SD 3.3/3.5
	PrimaConnex	RD 4.0/4.1		PrimaConnex	RD 4.0/4.1
	PrimaConnex	WD 5.0		PrimaConnex	WD 5.0
	Genesis	3.8, 4.5, 5.5/6.5		Genesis	3.8, 4.5, 5.5/6.5
Nobel Biocare	NobelActive	NP 3.5 – RP 4.3, 5.0	Nobel Biocare	NobelActive	NP 3.5 – RP 4.3, 5.0
	NobelReplace	NP-3.5 – RP 4.3 – WP 5.0 –		NobelReplace	NP-3.5 – RP 4.3 – WP 5.0 –
Straumann	Bone Level	3.3 NC – 4.1, 4.8 NC	Straumann	Bone Level	3.3 NC – 4.1, 4.8 NC
	Standard Plus	3.5 NN		Standard Plus	3.5 NN
	Standard / Standard Plus	4.8 RN – 4.8 WN		Standard / Standard Plus	4.8 RN – 4.8 WN
Zimmer Dental	Tapered Screw Vent / Screw Vent	Tapered S-V 3.5/S-V 3.3, 3.7 / Tapered S-V 4.5/ S-V 4.5	Zimmer Dental	Tapered Screw Vent	Tapered S-V 3.5/S-V 3.3, 3.7 / S-V 4.5/ S-V 4.5
	Tapered Screw Vent	5.7		Tapered Screw Vent	5.7
Abutments:			**Abutments**:		
Manufacturer	Name of Abutment		Manufacturer	Name of Abutment	
Biomet 3i	Low Profile Abutment		Biomet 3i	Low Profile Abutment	
DENTSPLY	ATIS Uni Abutment EV		DENTSPLY	ATIS Uni Abutment EV	
	ATIS UniAbutment 20°, ATIS UniAbutment 45°			ATIS UniAbutment 20°, ATIS UniAbutment 45°	
	ATIS Angled Abutment EV			ATIS Angled Abutment EV	
	ATIS Angled Abutment 20°			ATIS Angled Abutment 20°	
	ANKYLOS Balance Base Narrow D4.2, Balance			ANKYLOS Balance Base Narrow D4.2, Balance	
	ATIS Multibase Abutment EV			XiVE MP 3.4, MP 3.8, MP 4.5, MP 5.5	
	XiVE MP 3.4, MP 3.8, MP 4.5, MP 5.5			XiVE TG 3.4, TG 3.8, TG 4.5	
	XiVE TG 3.4, TG 3.8, TG 4.5				
Nobel Biocare	Multi-Unit Abutment RP		Nobel Biocare	Multi-Unit Abutment RP	
Straumann	Bone Level Multi-Base Angled Abutment		Straumann	Bone Level Multi-Base Angled Abutment	
	Bone Level Multi-Base Abutment D3.5, D4.5			Bone Level Multi-Base Abutment D3.5, D4.5	
	RN Abutment Level, WN Abutment Level			RN Abutment Level, WN Abutment Level	
	Screw-Retained Abutment 3.5, 4.6			Screw-Retained Abutment 3.5, 4.6	
Zimmer Dental	Tapered Abutment		Zimmer Dental	Tapered Abutment	

As shown in Table 3, the modification to the indications for use of the ATLANTIS™ Suprastructures which is subject to this premarket notification consists of the addition of the Astra Tech Implant System (ATIS) Multibase Abutment EV device to the list of compatible abutments. There are no other changes to the indications for use of the ATLANTIS™ Suprastructures as compared to the indications for use cleared previously under premarket notification K160207.

In order to support the substantial equivalence of the addition of compatibility with the Multibase Abutment EV devices to the indications for use of the ATLANTIS™ Suprastructures, geometric analysis of the abutment interface was included. The results of the analysis showed that the interface which facilitates compatibility with the Multibase Abutment EV devices does not present a new worst case with respect to cross-sectional material geometry and the modification therefore does not affect the substantial equivalence of the ATLANTIS™ Suprastructures.

Table 4: Similarities and Differences between the proposed and the predicate Suprastructures

	Proposed Device	**Predicate Device**
	Dentsply Sirona ATLANTIS™ Suprastructures	Dentsply Sirona ATLANTIS™ ISUS Implant Suprastructures K160207
Design		
Prosthesis Attachment	Screw-retained, Friction-fit	Screw-retained, Friction-fit
Design of Suprastructure	Bar, Bridge Hybrid 2 in 1	Bar, Bridge Hybrid 2 in 1
Platform diameter	3.0-6.5	3.0-6.5
Interface suprastructure-implant/ abutment	Internal, External	Internal, External
Material		
Suprastructure	CPTi, CoCr	CPTi, CoCr
Screw	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Delivery	sterile	sterile