March 3, 2020

Dentsply Sirona Inc.
Karl Nittinger
Vice President Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K193064
Trade/Device Name: Atlantis® suprastructures
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 3, 2019
Received: December 4, 2019

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K193064

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. Atlantis® suprastructures are compatible with following implants and abutments:

| **Manufacturer/** | **Implant system** |
|---|---|
| BioHorizons | **Implant Level** |
| | Internal/ Tapered 3.5, 4.5, 5.7 |
| | **Abutment Level** |
| | Multi-unit abutment |
| Biomet 3i | **Implant Level** |
| | Certain™ 3.25, 4.0, 4/3, 5.0, 5/4, 6.0 |
| | Certain™ Prevail™ 3/4/3 (3.4), 4/5/4, 5/6/5, 4/3, 5/4, 6/5 |
| | Certain™ XP 4/5, 5/6 |
| | **Abutment Level** |
| | Low Profile Abutment |
| Camlog | **Implant Level** |
| | Screw-line Implant 3.3 |
| | Screw-line/Root-line Implant 3.8, 4.3 |
| | Screw-line/Root-line Implant 5.0, 6.0 |
| Dentsply Sirona | **Implant Level** |
| | **Astra Tech Implant System®** |
| | Astra Tech Implant EV 3.0 – Green |
| | Astra Tech Implant EV 3.6 – Purple |
| | Astra Tech Implant EV 4.2 – Yellow |
| | Astra Tech Implant EV 4.8 – Blue |
| | Astra Tech Implant EV 5.4 – Brown |
| | Astra Tech Implant EV Profile 4.2 |
| | Astra Tech Implant EV Profile 4.8 |
| | OsseoSpeed® TX 3.0 – Yellow |
| | OsseoSpeed® TX 3.5, 4.0 – Aqua |
| | OsseoSpeed® TX 4.5, 5.0 – Lilac |
| | OsseoSpeed® TX Profile 4.5/5.0 |
| | **Xive®** |
| | Xive® S 3.0 |
| | Xive® S 3.4, 3.8, 4.5, 5.5 |
| | **Abutment Level** |
| | **Astra Tech Implant System®** |
| | UniAbutment EV |
| | Angled Abutment EV |
| | Multibase Abutment EV |
| | 20° UniAbutment |
| | 45° UniAbutment |
| | Angled Abutment 20° |
| | **Ankylos®** |
| | Ankylos® Balance Base Narrow D4.2 |
| | Ankylos® Balance Base D5.5 |

| | |
|---|---|
| | **Xive®** |
| | Xive® TG 3.4, 3.8, 4.5 |
| | Xive® MP 3.4, 3.8, 4.5 |
| | Xive® MP 5.5 |
| Keystone | **Implant Level** |
| | 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 |
| MIS | **Implant Level** |
| | Internal Hex Narrow SEVEN – M4 |
| | Internal Hex Standard SEVEN – M4 |
| | Internal Hex Wide SEVEN – M4 |
| | Conical Connection Narrow C1 – V3 |
| | Conical Connection Standard C1 – V3 |
| | Conical Connection Wide C1 |
| | **Abutment Level** |
| | Multi-Unit Abutment |
| Nobel Biocare | **Implant Level** |
| | NobelActive NP 3.5 |
| | NobelActive RP 4.3, 5.0 |
| | NobelActive WP 5.5 |
| | NobelReplace NP 3.5 |
| | NobelReplace RP 4.3 |
| | NobelReplace WP 5.0 |
| | NobelReplace 6.0 |
| | Branemark System NP 3.3 |
| | Branemark System RP 3.75, 4.0 |
| | **Abutment Level** |
| | Multi-Unit Abutment RP |
| Straumann | **Implant Level** |
| | Bone Level 3.3 NC |
| | Bone Level 4.1, 4.8 RC |
| | Standard/Standard Plus 4.8 RN (Regular Neck) |
| | Standard/Standard Plus 4.8 WN (Wide Neck) |
| | **Abutment Level** |
| | RN Abutment Level |
| | WN Abutment Level |
| | Bone Level Multi-Base Abutment D3.5, 4.5 |
| | Bone Level Multi-Base Angled Abutment |
| | Screw-Retained Abutment 3.5 |
| | Screw-Retained Abutment 4.6 |
| Zimmer Dental | **Implant Level** |
| | Tapered Screw-Vent™ 3.5, 4.5, 5.7 |
| | Screw Vent™ 3.3, 3.7, 4.5 |
| | **Abutment Level** |
| | 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.**

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Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

# 510(k) SUMMARY
# For K193064
# Atlantis® suprastructures

**1.** Submitter Information**:**

Dentsply Sirona Inc.
221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
Fax Number: 717-849-4343
Email: karl.nittinger@dentsplysirona.com

Date Prepared: 03 March 2020

2. Device Name:

- Proprietary Name: Atlantis® suprastructures
- Classification Name: Endosseous dental implant abutment
- CFR Number: 21 CFR 872.3630
- Device Class: Class II
- Product Code: NHA

3. Predicate Device:

Predicate Device for subject Atlantis suprastructures made by milling:

| **Predicate Device Name** | **510(k)** | **Company Name** |
|---|---|---|
| Multibase Abutments EV and ATLANTIS™ Suprastructures | K163350 | Dentsply Sirona |

Predicate Device for subject Atlantis suprastructures made by additive manufacturing:

| **Predicate Device Name** | **510(k)** | **Company Name** |
|---|---|---|
| ATLANTIS™ Suprastructures | K163398 | Dentsply Sirona |

Reference Devices:

| Reference Device Name | 510(k) | Company Name |
|---|---|---|
| ATLANTIS™ ISUS Implant Suprastructures | K160207 | Dentsply Sirona |
| BioHorizons Tapered Internal Implant System | K071638 | BioHorizons Implant Systems Inc. |
| BioHorizons Simple Solutions with Laser-Lok® | K100985 | BioHorizons Implant Systems, Inc. |
| MIS Internal Hex Dental Implant System | K180282 | MIS Implants Technologies Ltd. (Dentsply Sirona) |
| MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments | K172505 | MIS Implants Technologies Ltd. (Dentsply Sirona) |
| MIS V3 Conical Connection Dental Implant System | K163349 | MIS Implants Technologies Ltd. (Dentsply Sirona) |
| Conical Connection Implants | K112162 | MIS Implants Technologies Ltd. (Dentsply Sirona) |
| NobelActive Wide Platform (WP) | K133731 | Nobel Biocare AB |
| Various Branemark System Dental Implant Products | K022562 | Nobel Biocare AB |

4. Description of Device:

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. The subject Atlantis suprastructures include new compatible interfaces of the currently marketed Atlantis suprastructures made by milling (K163350) or additive manufacturing techniques (K163398) for the following abutments and implants:

BioHorizons Multi-unit abutment
MIS Internal Hex Narrow SEVEN – M4
MIS Internal Hex Standard SEVEN – M4
MIS Internal Hex Wide SEVEN – M4
MIS Conical Connection Narrow C1 – V3
MIS Conical Connection Standard C1 – V3
MIS Conical Connection Wide C1
MIS Multi-Unit Abutment
Nobel Biocare NobelActive WP 5.5
Nobel Biocare Branemark System NP 3.3
Nobel Biocare Branemark System RP 3.75, 4.0

The design of the subject 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 additive manufacturing (AM) to produce a customized, patient-specific device. The Atlantis suprastructures subject of this bundled premarket notification are fabricated by milling or by additive manufacturing techniques.

The milled Atlantis suprastructures are composed of commercially pure titanium (CPTi) or cobalt chrome alloy and are available in following design types: Bar, Bridge, Hybrid and 2 in 1. Additional design limitations regarding minimum required segment cross-section, maximum span between implants and maximum cantilever extension, have been introduced for Atlantis suprastructures made by milling.

Atlantis suprastructures made by additive manufacturing are provided as Bridge and Hybrid types with optional mechanical retention (pin or cell retention) on the surface. The manufacturing of the Bridges and Hybrids of the Atlantis suprastructures by an additive manufacturing technique start from a titanium alloy and a cobalt-chrome alloy in powder form.

Milled variants of the subject Atlantis® suprastructures are offered in versions composed of unalloyed titanium conforming to ASTM F67 (*Standard Specification for Unalloyed Titanium for Surgical Implant Applications*) and cobalt chromium alloy (CoCr) conforming to ISO 22674 (*Dentistry – Metallic materials for fixed and removable restorations and appliances*). Variants of the subject Atlantis® suprastructures which are fabricated utilizing additive manufacturing are manufactured using titanium alloy powder or cobalt chromium alloy powder conforming to ISO 22674 (*Dentistry – Metallic materials for fixed and removable restorations and appliances*).

Fixation screws for use with the subject Atlantis® suprastructures are composed of titanium alloy confirming to ASTM F136 (*Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*).

Screws are available for all compatible implants and abutments to screw the Atlantis suprastructures into the implant or onto the abutment.

Labeling is modified by providing a separate compatibility chart which lists all implants and abutments compatible with the Atlantis suprastructures.

5. Indications for Use:

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. Atlantis® suprastructures are compatible with the implants and abutments listed in the Atlantis® Suprastructures Compatibility Chart:

| Manufacturer/ | Implant system |
|---|---|
| BioHorizons | **Implant Level** |
| | Internal/ Tapered 3.5, 4.5, 5.7 |
| | **Abutment Level** |
| | Multi-unit abutment |
| Biomet 3i | **Implant Level** |
| | Certain™ 3.25, 4.0, 4/3, 5.0, 5/4, 6.0<br>Certain™ Prevail™ 3/4/3 (3.4), 4/5/4, 5/6/5, 4/3, 5/4, 6/5<br>Certain™ XP 4/5, 5/6 |
| | **Abutment Level** |
| | Low Profile Abutment |
| Camlog | **Implant Level** |
| | Screw-line Implant 3.3<br>Screw-line/Root-line Implant 3.8, 4.3<br>Screw-line/Root-line Implant 5.0, 6.0 |
| Dentsply Sirona | **Implant Level** |
| | **Astra Tech Implant System®**<br>Astra Tech Implant EV 3.0 – Green<br>Astra Tech Implant EV 3.6 – Purple<br>Astra Tech Implant EV 4.2 –<br>Yellow Astra Tech Implant EV 4.8<br>– Blue Astra Tech Implant EV 5.4 –<br>Brown Astra Tech Implant EV<br>Profile 4.2 Astra Tech Implant EV<br>Profile 4.8 OsseoSpeed® TX 3.0 –<br>Yellow OsseoSpeed® TX 3.5, 4.0 –<br>Aqua<br>OsseoSpeed® TX 4.5, 5.0 – Lilac<br>OsseoSpeed® TX Profile 4.5/5.0<br>**Xive®**<br>Xive® S 3.0 |
| | **Abutment Level** |
| | **Astra Tech Implant System®**<br>UniAbutment EV<br>Angled Abutment EV<br>Multibase Abutment EV<br>20° UniAbutment<br>45° UniAbutment<br>Angled Abutment 20°<br>**Ankylos®**<br>Ankylos® Balance Base Narrow D4.2<br>Ankylos® Balance Base D5.5 |
| | **Xive®**<br>Xive® TG 3.4, 3.8, 4.5<br>Xive® MP 3.4, 3.8, 4.5<br>Xive® MP 5.5 |

| | |
|---|---|
| Keystone | **Implant Level** |
| | 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 |
| MIS | **Implant Level** |
| | Internal Hex Narrow SEVEN – M4 |
| | Internal Hex Standard SEVEN – M4 |
| | Internal Hex Wide SEVEN – M4 |
| | Conical Connection Narrow C1 – V3 |
| | Conical Connection Standard C1 – V3 |
| | Conical Connection Wide C1 |
| | **Abutment Level** |
| | Multi-Unit Abutment |
| Nobel Biocare | **Implant Level** |
| | NobelActive NP 3.5 |
| | NobelActive RP 4.3, 5.0 |
| | NobelActive WP 5.5 |
| | NobelReplace NP 3.5 |
| | NobelReplace RP 4.3 |
| | NobelReplace WP 5.0 |
| | NobelReplace 6.0 |
| | Branemark System NP 3.3 |
| | Branemark System RP 3.75, 4.0 |
| | **Abutment Level** |
| | Multi-Unit Abutment RP |
| Straumann | **Implant Level** |
| | Bone Level 3.3 NC |
| | Bone Level 4.1, 4.8 RC |
| | Standard/Standard Plus 4.8 RN (Regular Neck) |
| | Standard/Standard Plus 4.8 WN (Wide Neck) |
| | **Abutment Level** |
| | RN Abutment Level |
| | WN Abutment Level |
| | Bone Level Multi-Base Abutment D3.5, 4.5 |
| | Bone Level Multi-Base Angled Abutment |
| | Screw-Retained Abutment 3.5 |
| | Screw-Retained Abutment 4.6 |
| Zimmer Dental | **Implant Level** |
| | Tapered Screw-Vent™ 3.5, 4.5, 5.7 |
| | Screw Vent™ 3.3, 3.7, 4.5 |
| | **Abutment Level** |
| | Tapered Abutment |

6. Substantial Equivalence:

An overview of the similarities and differences between the subject and predicate devices is given in Table 5.1 and 5.2 below.

The indications for use of the subject and predicate Atlantis suprastructures (K163350, K163398) are identical with respect to the clinical indications. The indications for use of the subject and predicate devices only differ regarding the compatible implants and abutments which are added by this 510(k) premarket notification. Design types, material, manufacturing techniques (milling, additive manufacturing), screw types (standard screw, Angulated Screw Access (ASA) as well as mechanical retention methods on the suprastructure surface (cell, pin) of the subject Atlantis suprastructures are the same as cleared for the predicate Atlantis suprastructures made by milling

(K163350) or additive manufacturing (K163398). The additional design limitations for some design types of milled Atlantis suprastructures (Non-Standard bar, 2 in1 primary structure, Hybrid, Bridge) are within the design parameters cleared for the predicate device (K163350). The design parameters cleared for the predicate Atlantis suprastructures made by additive manufacturing (K163398) remain unchanged for the subject device.

7. Non-Clinical Performance Data:

Following non-clinical test data and analyses are included to support substantial equivalence:

- Cross-sectional material analysis of the subject Atlantis suprastructure interfaces with the compatible implants and abutments, comparison to existing worst case interface geometry and reference to results of fatigue testing (K160207) conducted according to test methods of ISO 14801: *Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants*. *ISO 14801.*
- Geometric measurement data and statistical compatibility analysis of OEM implant bodies, OEM abutments, and OEM fixation screws, to support the compatibility of the subject Atlantis suprastructure interfaces with the compatible implants and abutments (K071638, K100985, K133731, K022562).
- Reference to process validation testing (K163398) for Atlantis suprastructures made by additive manufacturing.
- Reference by equivalence to validation of moist heat sterilization parameters conducted according to ISO 17665-1 *Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices* and ISO17665-2 *Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1.*
- Reference by equivalence to biocompatibility data of predicate devices (K163350, K163398).

8. Clinical Performance Data:

No human clinical data was included in this premarket notification to support the substantial equivalence of the subject Atlantis suprastructures.

9. Conclusion Regarding Substantial Equivalence:

The information included in this bundled 510(k) submission supports the substantial equivalence of the subject Atlantis suprastructures. The subject Atlantis suprastructures have the same intended use as the legally marketed predicate devices cleared under premarket notifications K163350 and K163398. The subject device also has similar indications for use and incorporates the same fundamental technology as the predicate devices (K163350, K163398). Results of technical analyses and compatibility studies to verify the performance of the subject Atlantis suprastructures support a determination of substantial equivalence.

Table 5.1: Indications for Use for the subject and the predicate devices

<table>
<tr><th>Subject Device</th><th>Indications for Use</th></tr>
<tr><td>Dentsply Sirona<br><br>Atlantis® suprastructures</td><td>
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.<br>
The Atlantis® suprastructures are compatible with the implants and abutments listed in the Atlantis® Suprastructures Compatibility Chart:
<table>
<tr><th>Manufacturer/ Company</th><th>Implant system</th></tr>
<tr><td>BioHorizons</td><td>Implant Level<br>Internal/ Tapered 3.5, 4.5, 5.7<br>Abutment Level<br>Multi-unit abutment</td></tr>
<tr><td>Biomet 3i</td><td>Implant Level<br>Certain™ 3.25, 4.0, 4/3, 5.0, 5/4, 6.0<br>Certain™ Prevail™ 3/4/3 (3.4), 4/5/4, 5/6/5, 4/3, 5/4, 6/5<br>Certain™ XP 4/5, 5/6<br>Abutment Level<br>Low Profile Abutment</td></tr>
<tr><td>Camlog</td><td>Implant Level<br>Screw-line Implant 3.3<br>Screw-line/Root-line Implant 3.8, 4.3<br>Screw-line/Root-line Implant 5.0, 6.0</td></tr>
<tr><td>Dentsply Sirona</td><td>Implant Level<br>Astra Tech Implant System®<br>Astra Tech Implant EV 3.0 – Green<br>Astra Tech Implant EV 3.6 – Purple<br>Astra Tech Implant EV 4.2 – Yellow<br>Astra Tech Implant EV 4.8 – Blue<br>Astra Tech Implant EV 5.4 – Brown<br>Astra Tech Implant EV Profile 4.2<br>Astra Tech Implant EV Profile 4.8<br>OsseoSpeed® TX 3.0 – Yellow<br>OsseoSpeed® TX 3.5, 4.0 – Aqua<br>OsseoSpeed® TX 4.5, 5.0 – Lilac<br>OsseoSpeed® TX Profile 4.5/5.0<br>Xive®<br>Xive® S 3.0<br>Xive® S 3.4, 3.8, 4.5, 5.5<br>Abutment Level<br>Astra Tech Implant System®<br>UniAbutment EV<br>Angled Abutment EV<br>Multibase Abutment EV<br>20° UniAbutment<br>45° UniAbutment<br>Angled Abutment 20°<br>Ankylos®<br>Ankylos® Balance Base Narrow D4.2<br>Ankylos® Balance Base D5.5<br>Xive®<br>Xive® TG 3.4, 3.8, 4.5<br>Xive® MP 3.4, 3.8, 4.5<br>Xive® MP 5.5</td></tr>
</table>
</td></tr>
</table>

Table 5.1: Indications for Use for the subject and the predicate devices (cont.)

| Subject Device | Indications for Use | |
|---|---|---|
| | Keystone Dental | **Implant Level** |
| | | 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 |
| | MIS | **Implant Level** |
| | | Internal Hex Narrow SEVEN – M4 |
| | | Internal Hex Standard SEVEN – M4 |
| | | Internal Hex Wide SEVEN – M4 |
| | | Conical Connection Narrow C1 – V3 |
| | | Conical Connection Standard C1 – V3 |
| | | Conical Connection Wide C1 |
| | | **Abutment Level** |
| | | Multi-Unit Abutment |
| | Nobel Biocare | **Implant Level** |
| | | NobelActive NP 3.5 |
| | | NobelActive RP 4.3, 5.0 |
| | | NobelActive WP 5.5 |
| | | NobelReplace NP 3.5 |
| | | NobelReplace RP 4.3 |
| | | NobelReplace WP 5.0 |
| | | NobelReplace 6.0 |
| | | Branemark System NP 3.3 |
| | | Branemark System RP 3.75, 4.0 |
| | | **Abutment Level** |
| | | Multi-Unit Abutment RP |
| | Straumann | **Implant Level** |
| | | Bone Level 3.3 NC |
| | | Bone Level 4.1, 4.8 RC |
| | | Standard/Standard Plus 4.8 RN (Regular Neck) |
| | | Standard/Standard Plus 4.8 WN (Wide Neck) |
| | | **Abutment Level** |
| | | RN Abutment Level |
| | | WN Abutment Level |
| | | Bone Level Multi-Base Abutment D3.5, 4.5 |
| | | Bone Level Multi-Base Angled Abutment |
| | | Screw-Retained Abutment 3.5 |
| | | Screw-Retained Abutment 4.6 |
| | Zimmer Dental | **Implant Level** |
| | | Tapered Screw-Vent™ 3.5, 4.5, 5.7 |
| | | Screw Vent™ 3.3, 3.7, 4.5 |
| | | **Abutment Level** |
| | | Tapered Abutment |

Table 5.1: Indications for Use for the subject and the predicate devices (cont.)

<table>
<tr><th>Predicate Devices</th><th><u>Indications for Use</u></th></tr>
<tr><td>Dentsply Sirona<br><br>Multibase Abutments EV and ATLANTIS™ Suprastructures<br><br>K163350</td><td>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:<br><br>Implants:
<table>
<tr><td>Manufacturer</td><td>Name of Implant</td><td>Size</td></tr>
<tr><td rowspan="4">Biomet 3i</td><td>Certain</td><td>3.25, 4/3 – Prevail ¾/3, 4/3</td></tr>
<tr><td>Certain</td><td>4.0, 5/4 – Prevail 4/5/4. 5/4</td></tr>
<tr><td>Certain</td><td>5.0, XP 4/5 – Prevail 5/6/5, 6/5</td></tr>
<tr><td>Certain</td><td>6.0, XP 5/6</td></tr>
<tr><td>BioHorizons</td><td>Internal/Tapered</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td rowspan="2">Camlog</td><td>Screw-line Implant</td><td>3.3</td></tr>
<tr><td>Screw-line / Root-line Implant</td><td>3.8, 4.3, 5.0, 6.0</td></tr>
<tr><td rowspan="5">DENTSPLY Implants</td><td>XiVE</td><td>S 3.0, S 3.4, S 3.8, S 4.5, S 5.5</td></tr>
<tr><td>OsseoSpeed™ TX</td><td>3.0, 3.5/4.0, 4.5/5.0</td></tr>
<tr><td>Osseospeed™ Profile TX</td><td>4.5/5.0</td></tr>
<tr><td>Osseospeed™ EV</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td></tr>
<tr><td>Osseospeed™ Profile EV</td><td>4.2, 4.8</td></tr>
<tr><td rowspan="4">Keystone Dental</td><td>PrimaConnex</td><td>SD 3.3/3.5</td></tr>
<tr><td>PrimaConnex</td><td>RD 4.0/4.1</td></tr>
<tr><td>PrimaConnex</td><td>WD 5.0</td></tr>
<tr><td>Genesis</td><td>3.8, 4.5, 5.5/6.5</td></tr>
<tr><td rowspan="2">Nobel Biocare</td><td>NobelActive</td><td>NP 3.5 – RP 4.3, 5.0</td></tr>
<tr><td>NobelReplace</td><td>NP-3.5 – RP 4.3 – WP 5.0 – 6.0</td></tr>
<tr><td rowspan="3">Straumann</td><td>Bone Level</td><td>3.3 NC – 4.1, 4.8 NC</td></tr>
<tr><td>Standard Plus</td><td>3.5 NN</td></tr>
<tr><td>Standard / Standard Plus</td><td>4.8 RN – 4.8 WN</td></tr>
<tr><td rowspan="2">Zimmer Dental</td><td>Tapered Screw Vent / Screw Vent*</td><td>Tapered S-V 3.5/S-V 3.3, 3.7 / Tapered S-V 4.5/ S-V 4.5</td></tr>
<tr><td>Tapered Screw Vent</td><td>5.7</td></tr>
<tr><td colspan="3">Abutments:</td></tr>
<tr><td>Manufacturer</td><td colspan="2">Name of Abutment</td></tr>
<tr><td>Biomet 3i</td><td colspan="2">Low Profile Abutment</td></tr>
<tr><td rowspan="8">DENTSPLY</td><td colspan="2">ATIS Uni Abutment EV</td></tr>
<tr><td colspan="2">ATIS UniAbutment 20°, ATIS Un</td></tr>
<tr><td colspan="2">ATIS Angled Abutment EV</td></tr>
<tr><td colspan="2">ATIS Angled Abutment 20°</td></tr>
<tr><td colspan="2">ANKYLOS Balance Base Narrow D4.2, Balance Base D5.5</td></tr>
<tr><td colspan="2">ATIS Multibase Abutment EV</td></tr>
<tr><td colspan="2">XiVE MP 3.4, MP 3.8, MP 4.5, MP 5.5</td></tr>
<tr><td colspan="2">XiVE TG 3.4, TG 3.8, TG 4.5</td></tr>
<tr><td>Nobel Biocare</td><td colspan="2">Multi-Unit Abutment RP</td></tr>
<tr><td>Straumann</td><td colspan="2">Bone Level Multi-Base Angled Abutment</td></tr>
<tr><td></td><td colspan="2">Bone Level Multi-Base Abutment D3.5, D4.5</td></tr>
<tr><td></td><td colspan="2">RN Abutment Level, WN Abutment Level</td></tr>
<tr><td></td><td colspan="2">Screw-Retained Abutment 3.5, 4.6</td></tr>
<tr><td>Zimmer Dental</td><td colspan="2">Tapered Abutment</td></tr>
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Table 5.1: Indications for Use for the subject and the predicate devices (cont.)

| Predicate Devices | Indications for Use |
|---|---|
| Dentsply Sirona<br><br>ATLANTIS™ Suprastructures<br><br>K163398 | 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.<br>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:<br>**Implants:**<br>• Biomet 3i Certain 3.25, 4/3 - Prevail 3/4/3, 4/3<br>• Biomet 3i Certain 4.0, 5/4 - Prevail 4/5/4, 5/4<br>• Biomet 3i Certain 5.0,XP4/5 - Prevail 5/6/5, 6/5<br>• Biomet 3i Certain 6.0, XP 5/6<br>• BioHorizons Internal/Tapered 3.5, 4.5, 5.7<br>• Camlog Screw-line Implant 3.3<br>• Camlog Screw-line / Root-line Implant 3.8, 4.3, 5.0, 6.0<br>• DENTSPLY Implants XiVE S 3.0, S 3.4, S 3.8, S 4.5, S 5.5<br>• DENTSPLY Implants OsseoSpeed TX 3.0, 3.5/4.0, 4.5/5.0<br>• DENTSPLY Implants OsseoSpeed Profile TX 4.5, 5.0<br>• DENTSPLY Implants OsseoSpeed EV 3.0, 3.6, 4.2, 4.8, 5,4<br>• DENTSPLY Implants OsseoSpeed Profile EV 4.2, 4.8<br>• Keystone Dental PrimaConnex SD 3.3, 3.5<br>• Keystone Dental PrimaConnex RD 4.0, 4.1<br>• Keystone Dental PrimaConnex WD 5.0<br>• Keystone Dental Genesis 3.8, 4.5, 5.5/6.5<br>• Nobel Biocare NobelActive NP 3.5 - RP 4.3, 5.0<br>• Nobel Biocare NobelReplace NP 3.5 - RP 4.3 - WP 5.0 - 6.0<br>• Straumann Bone Level 3.3 NC - 4.1, 4.8 RC<br>• Straumann Standard Plus 3.5 NN<br>• Straumann Standard/Standard Plus 4.8 RN - 4.8 WN<br>• Zimmer Dental Tapered S-V 3.5/ S-V 3.3, 3.7 /<br>Tapered S-V 4.5/ S-V 4.5<br>• Zimmer Dental Tapered Screw-Vent 5.7<br>**Abutments:**<br>• Biomet 3i Low Profile Abutment<br>• DENTSPLY Implants ATIS Uni Abutment EV<br>• DENTSPLY Implants ATIS UniAbutment 20°, ATIS UniAbutment 45°<br>• DENTSPLY Implants ATIS Angled Abutment EV,<br>ATIS Angled Abutment 20°<br>• DENTSPLY Implants Ankylos Balance Base Narrow D4.2,<br>Balance Base D5.5<br>• DENTSPLY Implants XiVE MP 3.4, MP 3.8, MP 4.5, MP 5.5<br>• DENTSPLY Implants XiVE TG 3.4, TG 3.8, TG 4.5<br>• Nobel Biocare Multi-Unit Abutment RP<br>• Straumann Bone Level Multi-Base Angled Abutment<br>• Straumann Bone Level Multi-Base Abutment D3.5, D4.5<br>• Straumann RN Abutment Level, WN Abutment Level<br>• Straumann Screw-Retained Abutment 3.5<br>• Straumann Screw-Retained Abutment 4.6<br>• Zimmer Dental Tapered Abutment |

Table 5.2: Similarities and Differences between the subject and the predicate devices

| | **Subject device** | **Predicate Devices** | |
|---|---|---|---|
| | Dentsply Sirona<br>Atlantis® suprastructures | Dentsply Sirona<br>Multibase Abutments EV and<br>ATLANTIS™ Suprastructures<br>K163350 | Dentsply Sirona<br>ATLANTIS™ Suprastructures<br>K163398 |
| **Design** | | | |
| Restoration | multi-unit | multi-unit | multi-unit |
| Design type | Bar, Bridge, Hybrid, 2 in 1 | Bar, Bridge, Hybrid, 2 in 1 | Bridge, Hybrid |
| Prosthesis attachment | screw-retained, friction fit (2in1) | screw-retained, friction fit (2in1) | screw-retained, friction fit (2in1) |
| Connection suprastructure – implant/abutment | internal, external | internal, external | internal, external |
| Design Technology | CAD/CAM (Milling, Additive Manufacturing (AM)) | CAD/CAM (Milling) | CAD/CAM (Additive Manufacturing) (AM) |
| Design parameters Standard Bar Micro/ Standard Bar Macro<br>Maximum span between implants<br>Maximum cantilever extension<br>Minimum cross-section connection | <br>20 mm/ 40 mm<br>6 mm/ 8 mm<br>2,5 $mm^2$/ 4.98 $mm^2$ | <br>20 mm/ 40 mm<br>6 mm/ 8 mm<br>2,5 $mm^2$/ 4.98 $mm^2$ | <br><br>N/A |
| Design parameters Non-Standard bar, 2 in1 primary structure, Hybrid (milled), Bridge (milled):<br>Maximum span between implants<br>Maximum cantilever extension<br>Minimum cross-section connection | <br><br>40 mm<br>15 mm<br>2.5 $mm^2$/ 4.98 $mm^2$/<br>4.0 mm height, 3.0 mm width* | <br><br>40 mm<br>15 mm<br>4.0 mm height, 3.0 mm width | <br><br>N/A |
| Design parameters Bridge and Hybrid (AM)<br>Maximum span between implants<br>Minimum cross-section connection<br>Maximum cantilever extension | <br>40 mm<br>15 mm<br>4.0 mm height, 3.0 mm width | <br><br>N/A | <br>40 mm<br>15 mm<br>4.0 mm height, 3.0 mm width |

*2.5 $mm^2$: if span between implants 0 to 20 mm or cantilever 0 to 6 mm), 4.98 $mm^2$: if span between implants >20 to 40 mm or cantilever >6 to 8 mm), 4.0 mm height, 3.0 mm width: if cantilever >8 to 15 mm

Table 5.2: Similarities and Differences between the subject and the predicate devices (cont.)

| | **Subject device** | **Predicate Devices** | |
|---|---|---|---|
| | Dentsply Sirona<br>Atlantis® suprastructures | Dentsply Sirona<br>Multibase Abutments and ATLANTIS™ Suprastructures<br>K163350 | Dentsply Sirona<br>ATLANTIS™ Suprastructures<br>K163398 |
| Mechanical retention | no retention<br>Cell or pin retention (optional for AM) | no retention | Cell or pin retention (optional) |
| Screws | Standard screws<br>Angulated Screw Access (ASA) screws | Standard screws<br>Angulated Screw Access (ASA) screws | Standard screws<br>Angulated Screw Access (ASA) screws |
| **Material** | | | |
| Abutment/ suprastructure | Commercially pure titanium (block)<br>Titanium alloy (powder)<br>Cobalt-chrome alloy (block, powder) | Commercially pure titanium (block)<br>Titanium alloy (powder)<br>Cobalt-chrome alloy (block, powder) | Commercially pure titanium (block)<br>Titanium alloy (powder)<br>Cobalt-chrome alloy (block, powder) |
| Prosthetic screw | Titanium alloy block | Titanium alloy block | Titanium alloy block |