



July 18, 2018

Dentsply Sirona
Karl Nittinger
Director, Corporate Regulatory Affairs
221 W Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K181189
Trade/Device Name: ATLANTIS® Conus Structure
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 1, 2018
Received: May 3, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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

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

Indications for Use

510(k) Number (if known)

K181189

Device Name

ATLANTIS® Conus Structure

Indications for Use (Describe)

The ATLANTIS® Conus Structure is indicated for attachment to ATLANTIS® Conus abutment, Overdenture (OD) via prefabricated SynCone 5° Taper caps (Degulor®) in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

The ATLANTIS® Conus Structure is intended for conical attachment to a minimum of four (4) ATLANTIS® Conus abutments, Overdenture (OD). The ATLANTIS® Conus Structure is only intended for acrylic or composite veneering.

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® Conus Structure

1. **Submitter Information:**

Dentsply Sirona
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York, PA 17401

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

Date Prepared: 17-July-2018

2. **Device Name:**

- Proprietary Name: ATLANTIS® Conus Structure
- Classification Name: Endosseous dental implant abutment.
- CFR Number: 21 CFR 872.3630
- Device Class: Class II
- Product Code: NHA (*Abutment, Implant, Dental Endosseous*)

3. **Predicate Device:**

The predicate and reference devices that have been identified relating to the substantial equivalence of the ATLANTIS® Conus Structure are:

| Predicate Device Name | 510(k) | Company Name |
|---|---------------|---------------------|
| ATLANTIS™ Suprastructures | K163398 | Dentsply Sirona |
| Reference Device Name | 510(k) | Company Name |
| OsseoSpeed™ Profile EV | K130999 | Dentsply Sirona |
| ATLANTIS™ Abutment for NobelActive 3.0 | K151039 | Dentsply Sirona |
| ATLANTIS™ Abutment for HIOSSEN ET implant | K160626 | Dentsply Sirona |
| ATLANTIS™ Abutment for CONELOG implant | K161030 | Dentsply Sirona |
| ATLANTIS™ Abutment for MIS implant | K172225 | Dentsply Sirona |
| ANKYLOS® SynCone® Abutment 5° | K131644 | Dentsply Sirona |

4. Description of Device:

The proposed ATLANTIS® Conus structure is a patient-specific endosseous dental implant support structure that is indicated for attachment to dental abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

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® Conus Structure is fabricated using additive manufacturing to produce a customized, patient-specific device.

The proposed ATLANTIS® Conus Structure is available in the following design types:

1. ATLANTIS® Conus Bridge – Intended for direct veneering using dental resin composites resulting in a removable friction-retained prosthesis. The bridge provides a full anatomical base for composite layering techniques.
2. ATLANTIS® Conus Hybrid – Intended as a removable friction-retained denture framework. The hybrid variant provides a surface with retention elements that can be finished with resin-based denture prosthesis.
3. ATLANTIS® Conus Base – Intended as a removable friction-retained denture framework for finishing with the resin-based denture prosthesis.

5. Indications for Use:

ATLANTIS® Conus Structure is indicated for attachment to ATLANTIS® Conus Abutment, Overdenture (OD) via prefabricated SynCone® 5° Taper caps (Degulor®) in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

The ATLANTIS® Conus Structure is intended for conical attachment to a minimum of four (4) ATLANTIS® Conus abutments, Overdenture (OD). The ATLANTIS® Conus Structure is only intended for acrylic or composite veneering.

6. Substantial Equivalence

Technological Characteristics

An overview of the similarities and differences between the proposed and predicate device is given in Table 1: Similarities and Differences between the proposed and the predicate device.

The subject ATLANTIS® Conus Structures are manufactured using the same materials (titanium alloy) and are produced using the identical additive manufacturing processes as are the primary predicate ATLANTIS™ Suprastructures (K163398) devices.

The proposed ATLANTIS® Conus Structure features the same design variants (Bridge and Hybrid) as the predicate device ATLANTIS™ Suprastructures (K163398). In addition to the Bridge and Hybrid variants, the proposed ATLANTIS® Conus Structure also features

the ATLANTIS® Conus Base variant which is a more basic version of the Hybrid as it does not have teeth retention elements on its surface nor the optional extra retention surface profile.

Additionally, the proposed ATLANTIS® Conus Structures which are the subject of this premarket notification feature the same options related to surface profile characteristics as do predicate ATLANTIS™ Suprastructures cleared in K163398. The optional cell retention and pin retention surface profiles of both the subject (with the exception of the subject device's "base" variant) and predicate devices are intended to enhance the surface area available for the mechanical retention of prosthetic materials that are applied to the underlying structures.

With respect to fundamental technology, the subject ATLANTIS® Conus Structures are identical to the primary predicate, the ATLANTIS™ Suprastructures (K163398), with the exception of the interface between the abutment / implant. The proposed ATLANTIS® Conus Structure is a removable structure (friction retained), while the predicate ATLANTIS™ Suprastructures (K163398) is a fixed structure (screw-retained).

While the primary predicate device (K163398) features pre-manufactured, implant-specific interface geometries to facilitate screw-retained connection to implants and abutments, the subject ATLANTIS® Conus Structures are intended for attachment to ATLANTIS® Conus abutments, Overdenture (OD) by friction retention via the currently marketed SynCone 5° Taper caps (Degulor®). The SynCone 5° Taper caps, cleared under reference device K131644, are cemented into recesses in the subject ATLANTIS® Conus Structures and facilitate the tapered friction-fit connection to the conical shape of the ATLANTIS™ Conus Abutment reference devices. The ATLANTIS™ Conus Abutment reference devices are specifically cleared for use with the SynCone 5° Taper caps for tapered friction-fit retention of removable prostheses in their clearances under K130999, K151039, K160626, and K172225. All technologies incorporated in the subject ATLANTIS® Conus Structures have been previously 510(k)-cleared; with the intended use and fundamental technologies cleared in the primary predicate device (K163398) and the tapered friction-fit method cleared in the reference devices, as listed in Section 3 of this 510(k) Summary.

Indications for Use Comparison

The difference in implant / abutment connection method between the subject ATLANTIS® Conus Structures and the primary predicate ATLANTIS™ Suprastructures (K163398) is reflected in the indications for use of the two devices. Because the connection method incorporated in the primary predicate device (K163398) is fixed (i.e., screw retention) and the connection geometries are manufactured to accommodate connection to specific implant and abutment systems, the indications for use of the primary predicate device (K163398) includes an overview of all implant and abutment systems. This is not applicable to the indications for use of the ATLANTIS® Conus Structures due to the fact that all of the ATLANTIS™ Conus Abutment reference devices, to which the subject

ATLANTIS® Conus Structures are friction-retained, feature the same, conical taper geometry which is compatible with the 5° internal taper of the SynCone® caps.

7. Non-Clinical Performance Data

Performance testing

For the proposed ATLANTIS® Conus Structure, non-clinical performance test data are included to support substantial equivalence:

- Dynamic fatigue tests on worst case test samples of the proposed ATLANTIS® Conus Structures, based on ISO 14801 *Dentistry - Implants - Dynamic fatigue test for endosseous dental implants*
- Testing in order to verify the bond strength of the SynCone® 5° Taper caps (Degulor®) and the ATLANTIS® Conus Structure when subjected to pull-off loads.
- Dimensional verification analysis of the conical connection cavities of the proposed ATLANTIS® Conus Structures to ensure correct fit with SynCone® 5° Taper caps (Degulor®).

Sterilization

The recommended sterilization method and validated sterilization parameters for the subject ATLANTIS® Conus Structures are identical to the sterilization method and validated parameters recommended for the primary predicate device (K163398). Therefore, no new summary sterilization validation information has been included to support substantial equivalence.

Biocompatibility

Because the subject ATLANTIS® Conus Structures are composed of the identical titanium alloy material and are manufactured utilizing the identical additive manufacturing processes, equipment, and process controls of the primary predicate device (K163398) no new biocompatibility testing has been included to support substantial equivalence.

An analysis was conducted to assess the potential for toxicological effects resulting from the interaction of materials. The results of the analysis concluded that, under worst-case conditions, no corrosion products of toxicological concern are released and thus support the biocompatibility and the substantial equivalence of the subject ATLANTIS® Conus Structures.

8. Clinical Performance Data

No clinical performance data were submitted in support of substantial equivalence.

9. Conclusion Regarding Substantial Equivalence

The proposed ATLANTIS® Conus Structure is intended to be used by dental clinicians in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function. The proposed ATLANTIS® Conus Structure has the same intended use, is composed of the same material, incorporates the same product and manufacturing

technology and has similar indications for use as the predicate device ATLANTIS™ Suprastructures (K163398).

Performance testing has been conducted and is included in this premarket notification to verify that the subject device meets its predetermined performance requirements and the results support a conclusion of substantial equivalence.

Table 1: Similarities and Differences between the proposed and predicate devices

| | <p align="center">Proposed device ATLANTIS® Conus Structures</p> | <p align="center">Predicate device ATLANTIS™ Suprastructures (K163398)</p> | <p align="center">Reference Device ANKYLOS® SynCone® Abutment 5° (K131644)</p> |
|-----------------------------------|---|--|---|
| <p>Indications for use</p> | <p>ATLANTIS® Conus Structure is indicated for attachment to ATLANTIS® Conus Abutment, Overdenture (OD) via prefabricated SynCone® 5° Taper caps (Degulor®) in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.</p> <p>The ATLANTIS® Conus Structure is intended for conical attachment to a minimum of four (4) ATLANTIS® Conus abutments, Overdenture (OD). The ATLANTIS® Conus Structure is only intended for acrylic or composite veneering.</p> | <p>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:</p> <p>Implants:</p> <ul style="list-style-type: none"> • 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 <p>Abutments:</p> <ul style="list-style-type: none"> • 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, 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 | <p>SynCone® Abutments on osseointegrated implants:</p> <p>Anchorage of dentures retained by taper friction and supported by ANKYLOS® implants.</p> <p>SynCone® Abutments for immediate loading:</p> <p>Immediate loading of an implant supported prosthesis in an edentulous mandible supported by 4 ANKYLOS® implants of at least 11 mm in length and placed interforaminally.</p> |

| Table 1 (continued): Similarities and Differences between the proposed and predicate devices | | | | |
|---|---|--|--|---|
| | Proposed device ATLANTIS® Conus Structures | Predicate device ATLANTIS™ Suprastructures (K163398) | Reference Device ANKYLOS® SynCone® Abutment 5° (K131644) | Summary of Differences |
| <u>Design</u> | | | | |
| Restoration | Multi-unit | Multi-unit | Multi-unit | No differences. |
| Design Type | Hybrid, Bridge, Base | Hybrid, Bridge | Individual endosseous dental implant abutments. | The proposed device is offered in a “base” variant, not offered in the predicate device. The “base” variant is identical to the hybrid variant with exception that it does not feature retention pins and is not offered with the mechanical retention surface profile. The reference devices (K131644) are standardized endosseous dental implant abutments which are included in relation to their use with the SynCone® 5° taper caps to facilitate friction retention of prosthetic restorations. |
| Prosthesis Attachment | Friction-retained via 5° SynCone® caps. | Screw-retained | Friction-retained via 5° SynCone® caps. | Predicate device (K163398) incorporates implant system-specific interface geometry to facilitate screw retention with implants. Proposed device does not interface directly with implants, instead, as does the reference device (K131644), relies on taper friction fit with currently marketed Conus abutments via currently marketed SynCone® caps. |
| Design Technology | CAD/CAM (Additive Manufacturing) | CAD/CAM (Additive Manufacturing) | Standardized abutment design. | No differences between proposed and predicate devices. The reference devices (K131644) are standardized endosseous dental implant abutments which are included in relation to their use with the SynCone® 5° taper caps to facilitate friction retention of prosthetic restorations. |
| Mechanical retention surface feature options | No retention (Base, Bridge, and Hybrid) Cell retention (Hybrid) Pin retention (Bridge and Hybrid) | No retention (Bridge and Hybrid) Cell retention (Hybrid) Pin retention (Bridge and Hybrid) | Not applicable. | No differences between the proposed device and predicate device. The reference devices (K131644) are standardized endosseous dental implant abutments which are included in relation to their use with the SynCone® 5° taper caps to facilitate friction retention of prosthetic restorations. |
| <u>Material</u> | | | | |
| Material | Titanium alloy | Titanium alloy, CoCr | Titanium alloy | While the predicate device (K163398) was cleared in both Ti alloy and CoCr materials, the proposed device is available in Ti alloy material only. |

Table 2: Summary comparison of ATLANTIS® Conus Structures and Reference Devices

| Proposed Device | Reference Devices | | | | | Summary of Differences |
|---|---|--|---|--|--|--|
| Dentsply Sirona ATLANTIS® Conus Structure | Dentsply Sirona OsseoSpeed™ Profile EV (K130999) | Dentsply Sirona ATLANTIS™ Abutment for NobelActive 3.0 (K151039) | Dentsply Sirona ATLANTIS™ Abutment for HIOSSEN ET implant (K160626) | Dentsply Sirona ATLANTIS™ Abutment for CONELOG implant (K161030) | Dentsply Sirona ATLANTIS™ Abutment for MIS Implant (K172225) | |
| Design | | | | | | |
| Prosthesis Attachment | | | | | | |
| Friction fit | Friction fit Screw-retained Cement-retained | Friction fit Screw-retained Cement-retained | Friction fit Screw-retained Cement-retained | Friction fit Screw-retained Cement-retained | Friction fit Screw-retained Cement-retained | Fundamentally, no difference. Both the proposed ATLANTIS® Conus Structures and the reference devices incorporate friction fit attachment and, to facilitate this friction fit attachment, the proposed and reference devices utilize the currently marketed SynCone® tapered caps. |
| Restoration | | | | | | |
| Multi-unit | Multi-unit Single unit | Multi-unit. Single unit. | Multi-unit. Single unit. | Multi-unit. Single unit. | Multi-unit. Single unit. | Fundamentally, no difference. The reference devices may be used for single-tooth prosthetic restoration, but also may be used in support of multi-unit prostheses via their ATLANTIS® Conus Abutment variants using the SynCone® caps. |
| Abutment Platform Diameter (mm) | | | | | | |
| N/A | 3.0, 4.3, 5.0 | 3.0 | 3.5, 4.0, 4.5, 5.0, 6.0, 7.0 | 3.3, 3.8, 4.3, 5.0 | 3.3, 3.75, 4.2, 5.0, 6.0 | This design element is not applicable to the proposed ATLANTIS® Conus Structures. |
| Abutment angulation | | | | | | |
| N/A | 0° - 30° | 0° - 30° | 0° - 30° | 0° - 30° | 0° - 30° | This design element is not applicable to the proposed ATLANTIS® Conus Structures. |
| Implant Connection Type | | | | | | |
| N/A | Internal | Internal | Internal | Internal | Internal | This design element is not applicable to the proposed ATLANTIS® Conus Structures. |

Table 2 (continued): Summary comparison of ATLANTIS® Conus Structures and Reference Devices

| Proposed Device | Reference Devices | | | | | Summary of Differences |
|---|---|---|---|---|---|---|
| Dentsply Sirona ATLANTIS® Conus Structure | Dentsply Sirona OsseoSpeed™ Profile EV (K130999) | Dentsply Sirona ATLANTIS™ Abutment for NobelActive 3.0 (K151039) | Dentsply Sirona ATLANTIS™ Abutment for HIOSEN ET implant (K160626) | Dentsply Sirona ATLANTIS™ Abutment for CONELOG implant (K161030) | Dentsply Sirona ATLANTIS™ Abutment for MIS implant (K172225) | |
| Material | | | | | | |
| Titanium alloy | Titanium alloy, Yttria Stabilized Zirconia | Titanium alloy | Titanium alloy, Yttria Stabilized Zirconia | Titanium alloy | Titanium alloy, Zirconia | No difference. The proposed ATLANTIS® Conus Structure is available only in titanium alloy material. The reference devices are available in the same titanium alloy material (although they are milled rather than fabricated by additive manufacturing), but are also available in zirconia ceramic material in some cases as noted. |