



Food and Drug Administration
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August 26, 2016

Dentsply Sirona
Ms. Helen Lewis
Director Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

Re: K161030
Trade/Device Name: ATLANTIS™ Abutment for CONELOG Implant
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 27, 2016
Received: July 29, 2016

Dear Ms. 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,

 Tina Kiang -
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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)
K161030

Device Name
ATLANTIS™ Abutment for CONELOG implant

Indications for Use (Describe)

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 prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS Abutment to the endosseous implant.

The ATLANTIS™ Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS Crown Abutment to the endosseous implant.

The ATLANTIS™ Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS Conus Abutment to the endosseous implant.

ATLANTIS™ products are compatible with the implants shown in the table below.

Implant Manufacturer	Trade Name	Implant Diameter	Abutment Platform Diameter
Altatec GmbH	CONELOG SCREW-LINE Implant	Ø3.3, 3.8, 4.3, 5.0 mm	Ø3.3, 3.8, 4.3, 5.0 mm

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 60
York, PA 17404



SECTION 5. 510(k) SUMMARY
for
ATLANTIS™ Abutment for CONELOG implant

1. Submitter Information:

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

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

Date Prepared: August 18, 2016

2. Device Name:

- Proprietary Name: ATLANTIS™ Abutment for CONELOG implant
- Classification Name: Endosseous dental implant abutment
- CFR Number: 21 CFR 872.3630
- Device Class: II
- Product Code: NHA

3. Predicate Device:

Predicate Device Name	510(k)	Company Name
ATLANTIS™ Abutment for NobelActive 3.0 (Primary Predicate Device)	K151039	DENTSPLY IMPLANTS MANUFACTURING GMBH
Osseospeed™ Profile EV (Reference Predicate Device)	K130999	DENTSPLY IMPLANTS MANUFACTURING GMBH
CONELOG Implant System (Reference Predicate Device)	K113779	Altatec GmbH

4. Description of Device:

The proposed *ATLANTIS™ Abutment for CONELOG implant* is an endosseous dental implant abutment. The subject device is provided for implant diameter (Ø3.3, 3.8, 4.3 and 5.0 mm) and three designs: ATLANTIS™ Abutment for CONELOG implant, ATLANTIS™ Crown Abutment for CONELOG implant and ATLANTIS™ Conus Abutment for CONELOG implant, see table 5-1. All are patient-specific abutments fabricated using CAD/CAM technology at DENTSPLY Implant sites. Each abutment is designed according to prescription instructions from the clinician to support a screw-retained, cement-retained or friction fit prosthesis.

Table 5-1: Compatibility table (The ATLANTIS Abutment Titanium and Gold-shaded are compatible with CONELOG implant interface (Ø3.3, 3.8, 4.3 and 5.0 mm))

Implant Manufacturer	Interface	ATLANTIS™ Abutment for CONELOG implant	ATLANTIS™ Crown Abutment for CONELOG implant	ATLANTIS™ Conus Abutment for CONELOG implant (Custom)	ATLANTIS™ Conus Abutment for CONELOG implant (Overdenture)
Altatec GmbH	CONELOG Implant System (SCREW- LINE) (Ø3.3, 3.8, 4.3 and 5.0 mm)	Titanium, Gold-shaded titanium (Gold-Hue)	Titanium	Titanium	Titanium

The coronal portion of the ATLANTIS™ Abutment can be fabricated as a conventional abutment for prosthesis attachment (ATLANTIS™ Abutment or ATLANTIS™ Conus Abutment) or fabricated as a single tooth final restoration onto which porcelain is added (ATLANTIS™ Crown Abutment). The ATLANTIS™ abutment interface is compatible with the CONELOG implants from the CONELOG Implant System (K113779).

The CONELOG implant interface is an internal conical connection with indexing feature (three grooves) and provided for implant platform diameter (3.3, 3.8, 4.3 and 5.0 mm). The abutment diameter ranges from 3.3 to 13 mm, the maximum abutment height is 15 mm above implant interface and the minimum abutment height is 4 mm above the transmucosal collar. The abutment is provided straight and up to 30° of angulation.

5. Indications for Use:

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 prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS Abutment to the endosseous implant.

The **ATLANTIS™ Crown Abutment** is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS Crown Abutment to the endosseous implant.

The **ATLANTIS™ Conus Abutment** is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS Conus Abutment to the endosseous implant.

ATLANTIS™ products are compatible with the implants shown in the table below.

Implant Manufacturer	Trade Name	Implant Diameter	Abutment Platform Diameter
Altatec GmbH	CONELOG SCREW-LINE Implant	Ø3.3, 3.8, 4.3, 5.0 mm	Ø3.3, 3.8, 4.3, 5.0 mm

6. Substantial Equivalence:

Technological Characteristics

ATLANTIS™ Abutment for CONELOG implant is a patient specific restorative device designed under the control of DENTSPLY and manufactured by DENTSPLY using CAD/CAM technology.

Table 5-2 and 5-3 below summarizes the differences and similarities of the subject and predicate devices.

Table 5-2: Indications for use for the proposed and the predicate devices

ATLANTIS™ Abutment for CONELOG implant (Proposed Device)	ATLANTIS™ Abutment for NobelActive 3.0 (K151039) (Primary Predicate)	OsseoSpeed Profile EV (K130999) (Reference Predicate)	CONELOG Implant System (K113779) (Reference Predicate)	Summary of differences in the indications for use
<p>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 prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS Abutment to the endosseous implant.</p> <p>The ATLANTIS™ Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS Crown Abutment to the endosseous implant.</p> <p>The ATLANTIS™ Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS Conus Abutment to the endosseous implant.</p>	<p>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 prosthesis, in the mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS™ Abutment to the endosseous implant.</p> <p>The ATLANTIS™ Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS™ Crown Abutment to the endosseous implant.</p> <p>The ATLANTIS™ Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially</p>	<p>Implants:</p> <p>The ASTRA TECH Implant System – OsseoSpeed Profile EV implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:</p> <ul style="list-style-type: none"> • 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 us in soft bone applications where implant surface treatment 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 	<p>CONELOG® Implant System Implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch.</p> <p>CONELOG® Implant System Abutments are intended for use as support for crowns, bridges or overdentures. 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.</p> <p>CONELOG® Implants with Ø3.3 mm diameter have the following additional specific indications: These are an alternative in cases where the alveolar ridge width is only 5 - 6 mm. Because of their lower mechanical strength compared with larger diameter implants, they should only be used under the following conditions:</p> <ul style="list-style-type: none"> • As single implants, they should be used only to replace mandibular incisors and/or maxillary lateral incisors. • An edentulous arch can only be restored with a bar retained superstructure with at least four implants of Ø3.3 mm diameter without distal extensions. • Implants of Ø3.3 mm are suitable for a partially edentulous arch when 	<p>The indications for use of the proposed device are identical to the indications for use of the primary predicate device.</p> <p>The indications for use of the proposed device are similar to the indications for use of the reference predicate device (K130999). The difference is that the reference predicate device (K130999) also includes the indications for use of the implants, which is not the subject of this submission.</p> <p>The indications for use of the second reference predicate device cover the CONELOG implant system (K113779). The indications for use are similar. The difference between the proposed device and the reference predicate device (K113779) is that the prosthesis, in addition to screw-retained restoration or cement-retained restoration, can be attachment-retained (by friction-fit) to the proposed device.</p>

ATLANTIS™ products are compatible with the implants shown in the table below.

Implant Manufacturer	Trade Name	Implant Diameter	Abutment Platform Diameter
Altatec GmbH	CONELOG SCREW-LINE Implant	Ø3.3, 3.8, 4.3, 5.0 mm	Ø3.3, 3.8, 4.3, 5.0 mm

or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS™ Conus Abutment to the endosseous implant.

ATLANTIS™ Abutment for NobelActive 3.0 is compatible with the NobelActive 3.0 implant.

appropriate

- Only together with Profile EV components, Implant Driver Profile EV, Radiographic Implant Guides Profile EV and non-Indexed prosthetic components

Abutments:

ASTRA TECH Implant System™-OsseoSpeed EV abutments are intended to be used in conjunction with ASTRA TECH Implant System™-OsseoSpeed EV in fully edentulous or partially edentulous maxillary and/or mandibular arches.

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** 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

combined with implants of larger diameter for splinted superstructures. However, the limited strength of the implants with Ø3.3 mm must be taken into account.

- Avoid excessive mechanical stressing of the implants when using ball abutments in combination with Ø3.3 mm implants.
- The healing time for Ø3.3 mm implants is at least 12 weeks.

CONELOG® Implants with 7 mm length have the following additional specific indications:
CONELOG® SCREW-LINE Implants should only be used when there is not enough space for a longer implant. Delayed loading in single tooth replacement is indicated with these implants. If the ratio of crown length to implant length is unfavorable the biomechanical risk factors have to be considered and appropriate measures have to be taken by the dental professional.

		<p>screw retained. The abutment screw is intended to secure the ATLANTIS™ Abutment to the endosseous implant.</p> <p>The ATLANTIS Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS Abutment to the endosseous implant.</p> <p>ATLANTIS™ Abutment, ATLANTIS™ Crown Abutment and ATLANTIS™ Conus Abutment are compatible with ASTRA TECH Implant System Profile EV</p>		
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Table 5-3: Similarities and differences between the proposed and the predicate devices

Element	Proposed Device ATLANTIS™ Abutment for CONELOG implant	Primary Predicate Device ATLANTIS™ Abutment for NobelActive 3.0	Reference Predicate Device OsseoSpeed Profile EV	Reference Predicate Device CONELOG Implant System	Summary of differences
510(k)	To be assigned	K151039	K130999	K113779	-
Prosthesis Attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained	No difference between the proposed device and the primary predicate and the reference device (K130999).
Restoration	Single or Multi-unit	Single or Multi-unit	Single or	Single or Multi-unit	No difference.
Abutment Platform Diameter	3.3, 3.8, 4.3, 5.0	3.0	3.0, 4.2, 4,8	3.3, 3.8, 4.3, 5.0	The proposed abutment platform is designed to fit the reference predicate device (K113779). The proposed device encompasses the same range of physical dimensions; diameter, height and angle of abutments for the primary predicate as for the reference predicate (K113779). The subject abutment platform is not designed to fit the primary predicate device (K151039) or the reference predicate device (K130999).
Abutment angle	Straight, up to 30°	Straight, up to 30°	Straight, up to 30°	Straight, up to 30°	No difference.

Element	Proposed Device ATLANTIS™ Abutment for CONELOG implant	Primary Predicate Device ATLANTIS™ Abutment for NobelActive 3.0	Reference Predicate Device OsseoSpeed Profile EV	Reference Predicate Device CONELOG Implant System	Summary of differences
Connection	Internal conical connection	Internal conical connection	Internal conical connection	Internal conical connection	<p>The internal conical connection is similar for the proposed device when compared to the primary predicate device (K151037) or the reference predicate device (K130999).</p> <p>The connection of the proposed device is designed to fit the reference predicate (K113779).</p>
Material Implant	NA	NA	Titanium	Titanium	The proposed device and primary predicate is an abutment.
Material: Abutment	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy	No difference.
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy	No difference.

7. Biocompatibility

The results of biocompatibility testing conducted for the primary predicate device, ATLANTIS™ Abutment for NobelActive 3.0 (K151039), are valid because the material composition of the proposed device is the same when compared to the primary predicate device, ATLANTIS™ Abutment for NobelActive 3.0 (K151039). Atlantis abutments are made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401). As per our biological evaluations on the titanium materials used for the ATLANTIS Abutment (RP-00054490), the following tests were performed: Cytotoxicity, Sensitization, Irritation of Intracutaneous reactivity, Acute systemic toxicity, Subchronic toxicity, Genotoxicity – AMES, and Hemolysis. Since the material composition of the proposed devices is identical to the predicate devices, the result of referenced biocompatibility testing is still valid. Therefore, no additional biocompatibility testing has been performed.

8. Sterility

The sterility testing conducted for the primary predicate device, ATLANTIS™ Abutment for NobelActive 3.0 (K151039), was conducted with the same materials and same sterilization cycle. Therefore, no additional sterility testing was required for the proposed device, ATLANTIS™ Abutment for CONELOG implant.

9. 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 *Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants*.

Compatibility analysis shows that the ATLANTIS™ Abutment for CONELOG implant is compatible with the (3.3, 3.8, 4.3 and 5.0 mm) CONELOG implants. Mechanical testing results show that the ATLANTIS™ Abutment for CONELOG implant has sufficient strength for its intended use.

9. Conclusion Regarding Substantial Equivalence

The ATLANTIS™ Abutment for CONELOG implant is an endosseous dental implant abutment which is intended to support a prosthetic device in a partially or completely edentulous patient. The ATLANTIS™ Abutment for CONELOG implant has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicates ATLANTIS™ Abutment for NobelActive 3.0 (K151039), Osseospeed Profile EV (K130999) and CONELOG Implant System (K113779).

Test data to verify the performance of the ATLANTIS™ Abutment for CONELOG implant has been provided including: mechanical testing and compatibility analysis. The results of this testing, combined with the design, and intended use comparison with the predicate devices, support substantial equivalence.