



Food and Drug Administration
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January 14, 2016

DENTSPLY International, Inc.
Ms. Helen Lewis
Director of Corporate Regulatory Affairs
Susquehanna Commerce Center
221 W. Philadelphia St., Suite 60
York, Pennsylvania 17401

Re: K151039

Trade/Device Name: ATLANTIS™ Abutment for NobelActive 3.0

Regulation Number: 21 CFR 872.3630

Regulation Name: Endosseous Dental Implant Abutment

Regulatory Class: II

Product Code: NHA

Dated: December 10, 2015

Received: December 14, 2015

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
-S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K151039

Device Name: ATLANTIS™ Abutment for NobelActive 3.0

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 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.

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



510(k) SUMMARY
for
ATLANTIS™ Abutment for NobelActive 3.0

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1. Submitter Information:

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Susquehanna Commerce Center
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York, PA 17401

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

Date Prepared: 12 January 2015

2. Device Name:

- Proprietary Name: ATLANTIS™ Abutment for NobelActive 3.0
- Classification Name: Endosseous dental implant abutment
- CFR Number: 21 CFR 872.3630
- Device Class: Class II
- Product Code: NHA

3. Predicate Devices:

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

Table 3.1		
Predicate Device Name	510(k)	Company Name
ATLANTIS™ Abutment for Nobel Biocare Active Implant (Primary Predicate Device)	K093483	Astra Tech Inc.*
OsseoSpeed Profile EV (Reference Predicate Device)	K130999	DENTSPLY Implants
NobelActive 3.0 (Reference Predicate Device)	K102436	Nobel Biocare AB

* = Astra Tech Inc. is the original applicant. 510(k) was transferred to DENTSPLY International Inc. after purchase of Astra Tech Inc.

4. Description of Device:

ATLANTIS™ Abutment for NobelActive 3.0 is provided in three designs: ATLANTIS™ Abutment for NobelActive, ATLANTIS™ Crown Abutment for NobelActive and ATLANTIS™ Conus Abutment for NobelActive. All are patient specific fabricated abutments using CAD/CAM technology. Each abutment is designed according to prescription instructions from the clinician to support a screw-retained, cement-retained or friction fit prosthesis.

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 implant/abutment interface is compatible with the NobelActive 3.0 implant.

ATLANTIS™ Abutment for NobelActive 3.0 has an internal conical connection and is provided for implant platform diameter Ø3.0 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 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.

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

6. Substantial Equivalence:

Technological Characteristics.

ATLANTIS™ Abutment for NobelActive 3.0 is a patient specific restorative device designed under the control of DENTSPLY and manufactured by DENTSPLY using CAD/CAM technology.

Table 6.1 below describes the differences and similarities of the subject and predicate devices.

Table 6.1				
	Subject Device	Predicate Devices		
	<p>DENTSPLY Implants</p> <p>ATLANTIS™ Abutment for NobelActive 3.0</p>	<p>Astra Tech, Inc.</p> <p>ATLANTIS™ Abutment for Nobel Biocare Active Implant</p> <p>K093483</p>	<p>DENTSPLY Implants</p> <p>OsseoSpeed™ Profile EV</p> <p>K130999</p>	<p>Nobel Biocare AB</p> <p>NobelActive 3.0</p> <p>K102436</p>
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 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</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 cement or screw retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. This device is compatible with the following manufacturers' implant systems: The titanium and zirconia abutments are compatible with the Nobel Biocare's NobelActive Implants.</p> <p>Please note: This</p>	<p>Implants: 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 use in soft bone applications where implants with other implant surface treatments may be less effective • immediate and early loading for all indications • together with immediate loading protocol 	<p>The NobelActive 3.0 mm implant is indicated for use. In the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, In order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.</p>

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	Subject Device	Predicate Devices		
	<p>DENTSPLY Implants</p> <p>ATLANTIS™ Abutment for NobelActive 3.0</p>	<p>Astra Tech, Inc.</p> <p>ATLANTIS™ Abutment for Nobel Biocare Active Implant</p> <p>K093483</p>	<p>DENTSPLY Implants</p> <p>OsseoSpeed™ Profile EV</p> <p>K130999</p>	<p>Nobel Biocare AB</p> <p>NobelActive 3.0</p> <p>K102436</p>
	<p>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>ATLANTIS™ Abutment for NobelActive 3.0 is compatible with the Ø3.0 mm Nobel Biocare</p>	<p>device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.</p> <p>Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.</p>	<p>in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate</p> <ul style="list-style-type: none"> • only together with Profile EV components, Implant Driver Profile EV, Radiographic Implant Guides Profile EV and non-Indexed prosthetic components <p>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.</p> <p>The ATLANTIS™ Abutment is</p>	

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	<p>DENTSPLY Implants</p> <p>ATLANTIS™ Abutment for NobelActive 3.0</p>	<p>Astra Tech, Inc.</p> <p>ATLANTIS™ Abutment for Nobel Biocare Active Implant</p> <p>K093483</p>	<p>DENTSPLY Implants</p> <p>OsseoSpeed™ Profile EV</p> <p>K130999</p>	<p>Nobel Biocare AB</p> <p>NobelActive 3.0</p> <p>K102436</p>
	NobelActive Implant.		<p>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.</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 partially or completely edentulous patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment</p>	

Table 6.1				
	Subject Device	Predicate Devices		
	<p>DENTSPLY Implants</p> <p>ATLANTIS™ Abutment for NobelActive 3.0</p>	<p>Astra Tech, Inc.</p> <p>ATLANTIS™ Abutment for Nobel Biocare Active Implant</p> <p>K093483</p>	<p>DENTSPLY Implants</p> <p>OsseoSpeed™ Profile EV</p> <p>K130999</p>	<p>Nobel Biocare AB</p> <p>NobelActive 3.0</p> <p>K102436</p>
			<p>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™ 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>	

Table 6.1				
	Subject Device	Predicate Devices		
	DENTSPLY Implants ATLANTIS™ Abutment for NobelActive 3.0	Astra Tech, Inc. ATLANTIS™ Abutment for Nobel Biocare Active Implant K093483	DENTSPLY Implants OsseoSpeed™ Profile EV K130999	Nobel Biocare AB NobelActive 3.0 K102436
Design				
Prosthesis Attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit
Abutment Diameter	3.0	3.5, 4.3, 5.0	3.0, 4.2, 4.8	3.0
Abutment Angle	Straight, up to 30°	Straight, up to 30°	Straight, up to 30°	Straight, up to 30°
Connection	Internal	Internal	Internal	Internal
Material				
Implant	NA	NA	Titanium	Titanium
Abutment	Titanium alloy	Titanium alloy, Zirconia	Titanium alloy, Zirconia	Titanium alloy
Screw	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy

Biocompatibility

The results of biocompatibility testing conducted for the predicate devices, ATLANTIS™ Abutment for Nobel Biocare Active Implant (K093483) and OsseoSpeed Profile EV (K130999), are valid, therefore, no additional biocompatibility testing has been performed.

Sterility

The results from the previous sterility testing are valid for the proposed device, ATLANTIS™ Abutment for NobelActive 3.0. The sterility testing conducted for the predicate devices, ATLANTIS™ Abutment for Nobel Biocare Active Implant (K093483) and OsseoSpeed Profile EV (K130999), was conducted with the same materials and same sterilization cycle. Therefore, no additional sterility testing was required.

7. Non-Clinical Performance Data.

Non-clinical testing data, 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 NobelActive 3.0 is compatible with the NobelActive 3.0 implant. Mechanical testing results show that the ATLANTIS™ Abutment for NobelActive 3.0 has sufficient strength for its intended use.

Conclusion Regarding Substantial Equivalence

The ATLANTIS™ Abutment for NobelActive 3.0 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 NobelActive 3.0 has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicate devices ATLANTIS™ Abutment for Nobel Biocare Active Implant (K093483), OsseoSpeed Profile EV (K130999) and NobelActive 3.0 (K102436).

The subject device when compared to the predicate devices support substantial equivalence.