

K112138

DEC - 1 2011

Premarket Notification  
Section 5: Page - 4

### 510(k) Summary

#### Astra Tech Inc. Atlantis™ Abutment in Zirconia for Astra Tech Osseospeed Plus Implant

#### ADMINISTRATIVE INFORMATION

**510K Summary preparation date:** July 13, 2011

**Manufacturer Name:** Astra Tech Inc.  
590 Lincoln Street  
Waltham, Massachusetts 02541  
Telephone: 781-810-6462  
Fax: 781-810-6719

**Official Contact:** Franklin Uyleman

**Representative/Consultant:** Betsy A. Brown  
B.A. Brown and Associates Inc.  
Telephone: 847-560-4406  
Fax: 847-677-0177

#### DEVICE NAME AND CLASSIFICATION

**Trade/Proprietary Name:** Atlantis™ Abutment in Zirconia for Astra Tech  
Osseospeed Plus Implant

**Common Name:** Endosseous dental implant abutment  
21 CFR 872.3630

**Product Code:** NHA

**Classification Panel:** Dental Products Panel

**Reviewing Branch:** Dental Devices Branch

#### INTENDED 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 abutment to the endosseous implant.

This device is compatible with the following manufacturers' implant systems:  
The Atlantis Abutment in Zirconia for Astra Tech Osseospeed Implant is compatible with the Astra Tech Osseospeed Plus 3.6mm and 4.2mm Implants.

**INTENDED USE (continued)**

Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.

Highly angulated abutments on small implants are intended for the anterior region of the mouth only.

**DEVICE DESCRIPTION**

The devices covered in this submission are abutments which are placed into the dental implant to provide support for a prosthetic restoration. The subject abutments are indicated for cemented or screw retained restorations. The **Atlantis™ Abutment in Zirconia for Astra Tech Osseospeed Plus Implant** for the Astra Tech Osseospeed Plus 3.6mm and 4.2mm Implants is made of biocompatible material, yttria-stabilized tetragonal for the zirconia polycrystals (Y-TZP) ( meets ISO Standards 6972 & 13356). Zirconia may have variation in shade. The **abutment screw** is made of Titanium grade Ti-6Al-4V ELI (meets ASTM Standard F-136). The zirconia abutments are placed over the implant shoulder and are mounted into the implant with a titanium screw.

**EQUIVALENCE TO MARKETED DEVICE**

Astra Tech Inc. demonstrated that, for purposes of the FDA's regulations of medical devices, the **Atlantis™ Abutment in Zirconia for Astra Tech Osseospeed Plus Implant** is substantially equivalent in indication and design principles to the abutment in Astra Tech's Implant System K#111287 and the Atlantis™ Abutment in Zirconia for Astra Implants K#071946 which has been determined by FDA to be substantially equivalent to preamendment devices.

### **Summary of Non-clinical Testing**

Static and fatigue compression testing was conducted on “worst case scenario” implant assemblies using Atlantis angled zirconia abutments with the Astra Tech Osseospeed Plus Implant. Test results demonstrated that the Atlantis Abutments are compatible with the Astra Tech Osseospeed Plus Implant and the implant system supported appropriate static and fatigue test loads demonstrating that the implant system performs as intended.

### **Conclusion for Substantial Equivalence:**

The Atlantis™ Abutment in Zirconia for Astra Tech Osseospeed Plus Implant is substantially equivalent to Astra Tech’s Implant System (Osseospeed) K#111287 and the Atlantis™ Abutment in Zirconia for Astra Implants cleared under K#071946 predicate devices, based on noted similarities in indication, manufacturing material, generated design principle and performance characteristics data.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Astra Technology, Incorporated  
C/O Ms. Betsy A. Brown  
Consultant  
B.A. Brown & Associates  
8944 Tamaroa Terrace  
Skokie, Illinois 60076

DEC - 1 2011

Re: K112138

Trade/Device Name: Atlantis™ Abutment in Zirconia for Astra Tech Osseospeed  
Plus Implant

Regulation Number: 21 CFR 872.3630

Regulation Name: Endosseous Dental Implant Abutment

Regulatory Class: II

Product Code: NHA

Dated: November 16, 2011

Received: November 21, 2011

Dear Ms. Brown:

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.

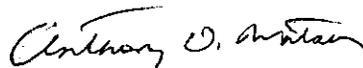
Page 2 – Ms. Brown

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known) K112138

Device Name: Atlantis™ Abutment in Zirconia for Astra Tech Osseospeed Plus Implant

Indication 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 abutment to the endosseous implant.

This device is compatible with the following manufacturers' implant systems:

The Atlantis Abutment in Zirconia for Astra Tech Osseospeed Implant is compatible with the Astra Tech Osseospeed Plus 3.6mm and 4.2mm Implants.

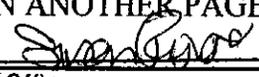
Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.

Highly angled abutments on small diameter implants are intended for the anterior region of the mouth only.

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) 

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K112138