K113003

MAR - 1 2012



**510(k) Summary**

**Astra Tech Inc.**
**Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Keystone Genesis Implant**

## ADMINISTRATIVE INFORMATION

**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
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## DEVICE NAME AND CLASSIFICATION

**Trade/Proprietary Name:** Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Keystone Genesis 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 endentulous 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 titanium and zirconia abutments are compatible with the 3.8mm, 4.5mm, 5.5mm, and 6.5mm Keystone Genesis Tapered and Straight Implants.

The Atlantis™ Crown Abutment in Zirconia 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 to the endosseous implant.

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

the 3.8mm, 4.5mm, 5.5mm, and 6.5mm Keystone Genesis Tapered and Straight 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.

## 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 titanium and zirconia abutments are indicated for cemented or screw retained restorations. The crown abutment in zirconia is indicated for screw retained restorations. The titanium **Atlantis™ Abutment for Keystone Genesis Implant** and **abutment screw** are made of Titanium grade Ti-6A1-4V ELI (meets ASTM Standard F-136) for the 3.8mm, 4.5mm, 5.5mm and 6.5mm sizes. In addition, the zircoina **Atlantis™ Abutment for Keystone Genesis Implant and the Atlantis™ Crown Abutment in Zirconia** for the 3.8mm, 4.5mm, 5.5mm and 6.5mm sizes are made of biocompatible material, yttria-stabilized tetragonal zirconia polycrystals (Y-TZP) and meets ISO Standards 6972 & 13356). Zirconia may have variation in shade. The titanium and 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 and the Atlantis™ Crown Abutment in Zirconia for Keystone Genesis Implant** are substantially equivalent in indications and design principles to Keystone's Genesis Implant System cleared under K#101545 and Astra Tech's Crown Abutment cleared

under K#110356, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

**Table 1: Substantial Equivalence Summary**

| **Technological Characteristics** | **Atlantis™ Abutment and Crown Abutment in Zirconia for Keystone Genesis Implant** | **Keystone Genesis Implant System K#101545** | **Astra Tech's Atlantis™ Crown Abutment in ZirconiaK#110356** |
|---|---|---|---|
| Material | -Titanium Alloy<br>-Biocompatible ceramic material | -Titanium Alloy | Titanium Alloy<br>-Biocompatible ceramic material |
| Performance characteristics | Allows the prosthesis to be cemented or screw retained to abutment. While the abutment screw is intended to secure the abutment to the endosseous implant. | Allows the prosthesis to be cemented or screw retained to abutment. While the abutment screw is intended to secure the abutment to the endosseous implant. | Allows the prosthesis to be screw retained to abutment. |
| Intended Use | Titanium & zirconia abutments:<br>Intended for use with an endosseous implant to support a prosthetic device in a partially or completely endentulous patient. Intended for use to support single or multiple tooth prosthesis, in mandible or maxilla.<br><br>Zirconia Crown Abutment: Intended for use with an endosseus implant to function as a substructure that also serves as the final restoration, in a partially or completely | Intended for use with an endosseous implant to support a prosthetic device in a partially or completely endentulous patient. Intended for use to support single or multiple tooth prosthesis, in mandible or maxilla. | Intended for use with an endosseus implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. It is intended to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant. |

| | | | |
|---|---|---|---|
| | edentulous patient. It is intended to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant. | | |

## Summary of Non-clinical Testing

Static and fatigue compression testing was conducted on "worst case scenario" implant assemblies using Atlantis angled titanium and zirconia abutments with the Keystone Genesis implant. Test results demonstrated that the Atlantis Abutments are compatible with the Keystone Genesis implants and the implant system supported appropriate static and fatigue test loads demonstrating that the implant system performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Astra Tech Incorporated
Ms. Betsy A. Brown
Regulatory Consultant
B.A. Brown & Associates
8944 Tamaroa Terrace
Skokie, Illinois 60076

MAR - 1 2012

Re: K113003
Trade/Device Name: Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Keystone Genesis Implant
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 20, 2012
Received: February 22, 2012

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.

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/CDRHOffices/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,

for 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) K113003

Device Name: Atlantis™ Abutment and Atlantis™ Crown Abutment in Zirconia for Keystone Genesis Implant

Indication for Use:

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Prescription Use___X___ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (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)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113003