SEP 2 8 2009

K091920

VII. SECTION 10 - 510(K) SUMMARY

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

1. **Applicant's Name and Address**

Astra Tech Inc.
590 Lincoln Street
Waltham, Massachusetts 02451
Telephone Number: 781-810-6462
Fax Number: 781-810-6719
Contact Person: Franklin Uyleman
Manager of Quality and Regulatory Affairs

2. **Name of Device**

Trade Name: Atlantis™ Abutment in Zirconia for Nobel Replace Implant
Common Name: Endosseous dental implant abutment
Classification Name: Endosseous dental implant abutment
21 CFR 872.3630 Product code NHA

3. **Legally Marketed Device to which Equivalence is claimed (Predicate Device)**

Manufacturer	Device	510(k) Number
Astra Tech Inc. (formerly Atlantis Components Inc.)	Atlantis™ Abutment in Zirconia for Nobel Replace Implant	K062277
Nobel Biocare	Replace TiUnite	K023113
Astra Tech Inc. (formerly Atlantis Componens zinc.)	Atlantis Abutment in Zirconia	K052070

4. Description of the Device

The devices covered in this submission are abutments which are placed into the dental implant to provide support for a prosthetic restoration. Zirconia may have a variation in shade. The subject abutments are indicated for cemented restorations. The **Atlantis™ Abutments in Zirconia for Nobel Replace Implants** and abutment screws are made from biocompatible yttria-stabilized tetragonal zirconia polycrystals (Y-TZP) and meets ISO Standards 6872 & 13356 and may be produced in any composition complying with the values specified by these standards.. The abutment screws are made from titanium grade Ti-6A1-V ELI and meets ASTM Standard F-136. The abutment is placed over the implant shoulder and is mounted into the implant with a screw. The abutments are compatible with Nobel Replace® Straight Groovy 3.5mm, Nobel Replace® Select Tapered and Straight 3.5mm, and NobelSpeedy™ 3.5mm implants.

5. Intended Use of the Device

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 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: Nobel Replace® Straight Groovy 3.5mm, Nobel Replace® Select Tapered and Straight 3.5mm and NobelSpeedy ™ 3.5mm 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 (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.

6. Basis for Substantial Equivalence

The **Atlantis™ Abutments in Zirconia for Nobel Replace Implants** are substantially equivalent in intended use, material, design and performance to the Atlantis Abutments in Zirconia cleared under K052070, Atlantis Abutments in Zirconia for Nobel Replace cleared under K062277 and Nobel Replace cleared under K023113.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 2 8 2009

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

Re: K091920
Trade/Device Name: Atlantis™ Abutment in Zirconia for Nobel Replace Implant
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 15, 2009
Received: June 30, 2009

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division 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) K091920

Device Name: Atlantis ™ Abutment in Zirconia for Nobel Replace Implant

Indication for Use:

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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 (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.

Prescription Use X AND/OR Over-The-Counter Use____
(Part 21 CFR 801 SubpartD) (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)

Kevin Mulley for HSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091920