K101004

AUG 16 2010

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.

Date of Summary preparation: April 1, 2010

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

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

2. **Name of Device**

Trade Name: Atlantis™ Abutment for Dentsply Ankylos 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
Dentsply International, Inc.	Ankylos C/X Dental Implant System	K083805
Astra Tech Inc.	Atlantis™ Abutment for Dentsply Implant	K093780

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. The subject abutments are indicated for cemented or screw retained restorations. The **Atlantis™ Abutment for Dentsply Ankylos Implant** and **abutment screw** are made from Titanium grade Ti-6A1-4V ELI (meets ASTM Standard F-136) for the 3.5mm, 4.5mm, 5.5mm, and 7.0mm sizes. The titanium abutments are placed over the implant shoulder and are mounted into the implant with a titanium screw.

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 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 abutments are compatible with the Dentsply 3.5mm, 4.5mm, 5.5mm and 7.0mm Ankylos 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 for Dentsply Ankylos Implants** are substantially equivalent in intended use, material, design and performance to the Dentsply Ankylos C/X Dental Implant System cleared under K083805 and the Astra Tech Inc., Atlantis™ Abutment for Dentsply Implant cleared under K093780.

Table 1:

Technological Characteristics	**Atlantis Abutment for Dentsply Ankylos Implants**	**Dentsply Ankylos C/X Implant System**
Material	Titanium alloy	Titanium alloy
Performance characteristics	Allows the prosthesis to be cemented or screw retained to the 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 the abutment. While the abutment screw is intended to secure the abutment to the endosseous implant
Intended Use	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 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.

Summary of Safety and Effectiveness Concerns

Safety and effectiveness problems that have been encountered with similar abutment systems used with endosseous implants that are currently being marketed include:

1. occasional fractures of the screw attaching the abutment to the fixtures usually due to functional overload from masticastory forces;

2 screw working loose (usually because torque force below recommended values was applied when the abutment attached to the fixture) may lead to the formation of granulation tissue at the level of the fixture and abutment connection which may, in turn, result in infection;

3. improper initial seating of the abutments resulting in gingival inflammation and fistulae formation both conditions resolve when proper seating of the abutment is accomplished;

4. occasional fracture of the abutment screw which is usually caused by poorly designed and/or fabricated restorations that creates overloads or causes metal fatigue.

Summary of Safety and effectiveness Studies (continued)

Summary of Safety and Effectiveness for Endosseous Implants for Prosthetic Attachments (Screw type/Two Stage

The endosseous (dental) implant is made of a material, such as titanium or ceramic, intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. The endosseous implant can be defined as a one stage or a tow stage implant system. These types include the blade, screw, solid cylinder, and hollow cylinder. These implant systems are composed of the implant (including the abutments) and accessories utilized in the fabrication and alignment of the abutment for successful attachment of the prosthesis.

The two stage endosseous implant is an implant that is composed of two or more components and incorporates at least two surgical phases to prepare the implant for prosthetic attachment. These two surgical phases are 1). The placement of the first stage component into the mandibular or maxillary bone and 2). Subsequent uncovering, at a later time defined by the labeling, of the first stage to allow attachment of the abutment and other components of the endosseous implant.

During the initial phase of healing, most implant system advocate that the fixtures should be submerged (2-stage surgical procedure). The reasons for this approach are 1). To minimize infection, 2). To prevent the apical downgrowth of mucosal epithelium and 3). To minimize the risk of undue early loading. This means that a second surgical session is requested to connect the installed fixtures to the mucosally piercing abutments before a supraconstruction can be connected and loading can be permitted. However, it has been demonstrated that correct clinical bone anchorage can also be achieved using a nonsubmerged approach (1-stage surgical procedure).

Clinical results indicate that fixtures ca be properly osseointegrated in mandibular bone using a 1-stage surgical approach and successfully used for bridge retention. In addition, comparing the data from 2- to 1-stage surgical procedure, it is obvious that a steady-state condition will be reached in the implant after 12 months, irrespective of the surgical approach used.

For patients using different medicines or suffering from different circulatory diseases or depression it might be especially advantageous to install the implant pillar using 1-stage surgical procedure and thus avoid a second surgical session. Age is another factor to consider in this respect, as well as some psychological aspects, e.g. fear of the surgical procedure.

The screw type implant is characterized as having a solid cylindrical core with a continuous screw thread that circumscribes the length of the solid cylindrical core. Principle initial anchorage is achieved by mechanical interlock of the screw threads. Long term fixation is obtained by a direct bone/implant interface without a significant percentage of interlining fibrous tissue.

Accessory components to an endosseous implant include copings, replicas, healing caps, drills, taps, burrs, etc. that are utilized for preparing the anatomical site for implantation, for abutment attachment, and for assisting in the fabrication of the final prosthesis.

Types of Safety and Effectiveness Problems

The type of safety and effectiveness problems identified below have been based on clinical database of information including all types of endosseous implants for prosthetic attachment (i.e. screw, blades, solid and hollow core cylinder endosseous implants). All of these risks are being included since the requirement of this summary is to identify all types of safety and effectiveness problems for the "generic" class of implants. These problems associated with endosseous implants for prosthetic attachment are based on two summary publications on this very subject. These publications are: Federal Register, Vol. 54, No. 234, pp. 50592-50595, December 7, 1989; and National Institutes of Health Consensus Development Conference Statement, "Dental Implants," Vol. 7, No. 3, June 15, 1988. The problems are:

1. paresthesia
2. perforation of maxillary sinus
3. perforation of labial and lingual plates
4. infectious endocarditis (in susceptible individuals)
5. air embolism
6. implant integrity (e.g. fracture, delamination of coating, biocompatibility, etc.)
7. local sift tissue degeneration
8. hyperplasia
9. progressive bone resorption
10. exfoliation
11. local and systemic infection (including long term bacterial infection)
12. Damage to existing dentition
13. implant mobility

Risks #1-5 are specific to the clinical placement of the implant (e.g. surgical procedure). These problems are reduced by adequate labeling and proper training of the clinician. Risk #6 depends both on the proper selection of implant material, implant design, proper placement of the implant(s) by the clinician, and properly designed, fabricated, and placed prosthetics. The remaining risks listed (#7-13) are affected by the implant material, implant design, proper placement of the implants by the clinician, properly designated/fabricated/placed prosthetics, and patient compliance/hygiene. The screw type implant is the only type of implant that has clinical studies to demonstrate the incidence of these problems.

Summary of Safety and Effectiveness for fixtures and components to Endosseous Implants

Safety and effectiveness problems that have been experienced with similar fixtures used with currently marketed endosseous implant systems include:

1. The lack of osseointegration of fixture, sometimes resulting from poor subject choice, or deviation from the recommended surgical protocol
2. Possible excessive bone loss, often due to poor surgical technique or excessive prosthetic loads
3. Wound dehiscence, due to the patient wearing a denture over operated site too soon after the procedure, pradiation therapy for an oral malignancy, previous surgery on the site or improper surgical technique
4. The potential of fracture of the fixture due to blunt trauma or occlusal overload,

Summary of Safety and Effectiveness for Dental Hand Instruments

Safety and effectiveness problems that have been experienced with similar dental hand instruments include:

1. Potential for some of the accessories to be aspirated or swallowed
2. Potential for fracture of the tip of the screwdriver machine instrument due to excessive pressure
3. Potential for slippage of the instrument causing minor laceration due to excessive pressure or poor dental technique

VIII. Substantial Equivalence

The **Atlantis™ Abutment for Dentsply Ankylos Implant** is part of an endosseous implant system designed for a single tooth or multiple unit bridge replacement. After a fixture has been inserted in the patient's jaw bone and the titanium abutment is attached to the fixture by means of an abutment screw. Atlantis abutment screw is designed to avoid the situation of having an abutment screw that is stronger than the implant such that the implant fails first. Ideally, with an abutment screw component that is weaker than the implant, the screw should fail first rather than the implant.

The **Atlantis Abutment for Dentsply Ankylos Implant** in titanium is substantially equivalent to the Dentsply Ankylos Dental Implant System presented in cleared 510K #083805 and the Astra Tech Inc., Atlantis Abutment for Dentsply Implant presented in cleared 510K #093780 in that the abutments respectively:

1. Allows the prosthesis to be cement or screw retained to the abutment. While the abutment screw is intended to secure the abutment to the endosseous implant.

2. These devices are used as connections with implant fixtures.

3. The Atlantis abutment in titanium, subject of this submission, are manufactured of titanium grade alloy Ti-6A1-4V ELI and when used with the Dentsply Ankylos implants, have the same performance characteristics of the predicate device abutment/implant systems.

As the above list of similarities indicates, the **Atlantis™ Abutments for Dentsply Ankylos Implant** and the predicate products have the same basic features, are made of equal material and are manufactured for the same general use.

We respectfully request FDA's concurrence with the conclusions noted above to support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

AUG 16 2010

Re: K101004
Trade/Device Name: Atlantis™ Abutment for Dentsply Ankylos Implant
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 2, 2010
Received: August 4, 2010

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

K101004

Indications for Use

AUG 16 2010

510(k) Number (if Known)_____

Device Name: Atlantis ™ Abutment for Dentsply Ankylos 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 cement or screw retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

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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)

Kim Mulay for MSR

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

510(k) Number: K101004