510(k) Summary

/53

Astra Tech AB
Special 510(k): Device Modification
K101005

JUN 2 1 2011

June 13, 2011

Astra Tech Implant System - New Components

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Astra Tech AB Aminogatan 1, P.O. Box 14 Mölndal, Sweden SE-431-21 Telephone: +46 31 776 30 00 Fax: +46 31 776 30 10
Official Contact:	Christina Lewing
Representative/Consultant:	Linda K. Schulz or Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: lschulz@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Astra Tech Implant System, New Components
Common Name:	Endosseous dental implant abutment
Classification Name:	Abutment, Implant, Dental, Endosseous (21 CFR 872.3630), Class II
Product Code:	NHA
Classification Panel:	Dental Products
Reviewing Branch:	Dental Devices

INTENDED USE

Astra Tech Implant System abutments are intended to be used in conjunction with the Astra Tech Implant System in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures. Highly angled abutments on small diameter implants are not recommended for use in the molar region. ZirDesign is not recommended for use in the molar regions.

DEVICE DESCRIPTION

The Astra Tech Implant System has been modified to increase treatment options by adding new abutment shapes in titanium and zirconia. Both abutment designs are provided in multiple sizes with straight and angled versions. The hex interlocking anti-rotation mechanism for indexing with the implant remains unchanged from the predicate devices. As with the predicate devices, Astra Tech's Conical Seal Design™ is used for the internal connection with the implant to achieve a tight and stable interface.

EQUIVALENCE TO MARKETED PRODUCT

K974738, K023631, K080396 – Astra Tech Implant System
K070833, K071946 – Atlantis System

The subject device and the predicate devices have the same intended use and have the same technological characteristics. Both are made of the same materials. They encompass the same range of physical dimensions, including diameter and length of the implants, and diameter, height and angle of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

Performance testing was provided to demonstrate substantial equivalence and included methods described in ISO 14801.

The modified Astra Tech Implant System has the following similarities to the unmodified predicate Astra Tech Implant System:

- has the same intended use,
- uses the same operating principle,
- are made from the same materials,
- incorporates the same basic design, and
- is packaged using the same materials and processes.

In summary, the modification to the Astra Tech Implant System described in this submission is, in our opinion, substantially equivalent to the predicate devices.

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 AB
C/O Ms. Linda K. Schulz
Paxmed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

JUN 21 2011

Re: K101005
Trade/Device Name: Astra Tech Implant System – New Component
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 13, 2011
Received: June 15, 2011

Dear Ms. Schulz:

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.

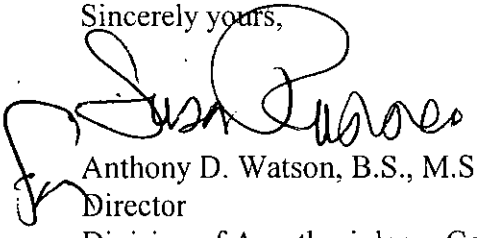
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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: K101005

Device Name: Astra Tech Implant System - New Components

Indications 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)

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

510(k) Number: K101005