

510(k) Summary

JAN 23 2013

**Astra Tech AB
OsseoSpeed™ Angled Abutment EV
K121810**

January 23, 2013

ADMINISTRATIVE INFORMATION

Manufacturer Name: Astra Tech AB
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: OsseoSpeed™ Angled Abutment EV
Common Name: Dental implant abutment
Classification Name: Endosseous dental implant abutment
Classification Regulation: Class II, 21 CFR 872.3630
Product Code: NHA
Classification Panel: Dental Products Panel
Reviewing Branch: Dental Devices Branch

INTENDED USE

OsseoSpeed™ Angled Abutment EV is intended to be used in conjunction with Astra Tech Implant System EV in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for bridges or overdentures.

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 prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

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.

Atlantis™ Abutment and Atlantis™ Crown Abutment are compatible with Ø5.4 Astra Tech Implant System EV.

DEVICE DESCRIPTION

OsseoSpeed Angled Abutment EV is designed for multi-unit, screw-retained restorations in a partially or fully edentulous situation. It is provided in three platform diameters (3.6, 4.2 and 4.8 mm) and two angles (20° and 30°). It is intended to fit Astra Tech implants of corresponding diameters cleared under K111287 and K120414. All abutments with a 20° angle are provided in two gingival heights (1.0 and 2.0 mm) with an indexed or non-indexed interface. All abutments with a 30° angle have a non-indexed interface and are provided in two gingival heights (1.0 and 3.0 mm).

OsseoSpeed Angled Abutment EV is not compatible with Astra Tech 3.0 mm diameter implants.

Atlantis Abutment in Zirconia for OsseoSpeed EV is a custom abutment for prosthesis attachment. Atlantis Crown Abutment in Zirconia for OsseoSpeed EV is fabricated as a custom single-tooth final restoration and is shaped in the design of the final prosthesis onto which porcelain is added. Both Atlantis abutments are provided in a platform diameter of 5.4 mm.

EQUIVALENCE TO MARKETED DEVICE

OsseoSpeed™ Angled Abutment EV is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Astra Tech AB - K111287
Astra Tech, Inc. - K112138
Astra Tech, Inc. - K110356

The purpose of this submission is to expand the OsseoSpeed Plus implant system to include three new components, the OsseoSpeed Angled Abutment EV, the Atlantis Abutment in Zirconia for OsseoSpeed EV, and Atlantis Crown Abutment in Zirconia for OsseoSpeed EV.

OsseoSpeed Angled Abutment EV is provided in two angles (20° and 30°). Platform sizes correspond to OsseoSpeed Plus implant diameters cleared in K111287. OsseoSpeed Angled Abutment EV is indicated for multi-unit restorations as are the predicate devices.

The original Atlantis Abutment in Zirconia for OsseoSpeed Plus was cleared in K112138 and the Atlantis Crown Abutment in Zirconia for OsseoSpeed was cleared in K110356. The interface remains the same as in K112138. A new size of Ø5.4 mm has been added for both designs.

Testing of OsseoSpeed™ Angled Abutment EV according to ISO 14801 *Dentistry - Implants - Dynamic fatigue test for endosseous dental implants*, was performed and the results show that OsseoSpeed™ Angled Abutment EV has sufficient mechanical strength for the intended clinical application and demonstrate that it is substantially equivalent to the listed predicate devices.

Overall, OsseoSpeed Angled Abutment EV has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes



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

January 23, 2013

Astra Tech AB
C/O Ms. Linda K. Schulz
Regulatory Affairs
PaxMed International, Limited Liability Company
12264 El Camino Real, Suite 400
SAN DIEGO CA 92130

Re: K121810
Trade/Device Name: OsseoSpeed™ Angled Abutment EV
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 2, 2013
Received: January 3, 2013

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,


Kwame O. Ulmer

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

Enclosure

Indications for Use

510(k) Number: K121810

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Atlantis™ Abutment and Atlantis™ Crown Abutment are compatible with Ø5.4 Astra Tech Implant System EV.

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)

Sheena A. Green
2013.01.23 16:10:12 -05'00'

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

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