

510(k) Summary
DENTSPLY Implants
OsseoSpeed™ Profile EV
K130999

September 23, 2013

OCT 25 2013

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	OsseoSpeed™ Profile EV
Common Name	Dental implant and abutment
Classification Name	Endosseous dental implant
Classification Regulations	Class II, 21 CFR 872.3640
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

Implants:

The ASTRA TECH Implant System – OsseoSpeed Profile EV implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

- replacing missing teeth in single or multiple unit applications in the mandible or maxilla.
 - immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge
 - especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective
 - immediate and early loading for all indications
 - together with immediate loading protocol in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate
 - only together with Profile EV components, Implant Driver Profile EV, Radiographic Implant Guides Profile EV and non-Indexed prosthetic components

Abutments

ASTRA TECH Implant System™ - OsseoSpeed™ EV abutments are intended to be used in conjunction with ASTRA TECH Implant System™ - OsseoSpeed™ EV in fully edentulous or partially edentulous maxillary and/or mandibular arches.

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 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.

The ATLANTIS™ Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS™ Abutment to the endosseous implant.

ATLANTIS™ Abutment, ATLANTIS™ Crown Abutment and ATLANTIS™ Conus Abutment are compatible with ASTRA TECH Implant System Profile EV.

DEVICE DESCRIPTION

The purpose of this submission is to expand the current OsseoSpeed EV Implant System (previously named OsseoSpeed Plus) to include the OsseoSpeed Profile EV implants. The OsseoSpeed EV Implant line is a part of the ASTRA TECH Implant System. The coronal contour of the OsseoSpeed Profile EV implant is designed to follow the anatomical contour of the bone and facilitate a more esthetic restoration.

Implants are available in a straight (cylindrical) design or with a taper at the implant neck. Each design is provided in two diameters (4.2 and 4.8 mm) and six lengths (8, 9, 11, 13, 15, and 17 mm).

Abutments are provided in titanium alloy and zirconia materials, Abutments have platform diameters of 3.0, 4.2, and 4.8 mm, prosthetic diameters from 3.3 to 7.0 mm, and gingival heights ranging from 2.0 to 6.5 mm. Abutments are provided straight and with up to 30° of angulation.

EQUIVALENCE TO MARKETED DEVICE

DENTSPLY Implants submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices OsseoSpeed™ Profile EV is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Astra Tech AB, OsseoSpeed™ Plus - K120414

Astra Tech AB, OsseoSpeed™ Profile, System - K080156

Astra Tech, Inc., Atlantis™ Abutment in Zirconia for OsseoSpeed TX Profile Implant - K103759

Astra Tech, Inc., Atlantis™ Abutment in Zirconia for Astra Tech Osseospeed Plus Implant - K112138

Astra Tech AB, Astra Tech Implant System, New Component - K072624

Astra Tech AB, Astra Tech Implant System - K101732

Atlantis Components, Inc. Atlantis™ Abutment for Astra Implant - K051652

FRIADENT GmbH, ANKYLOS® Dental Implant System – K041509

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject device and the predicate devices encompass the same range of physical dimensions and characteristics, including diameter, length, angulation and surface treatment. Any differences in the technological characteristics between the subject device and the predicate devices do not raise new issues of safety or efficacy.

Performance testing is provided to demonstrate substantial equivalence and includes static and dynamic compression-bending testing according to ISO 14801. The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, OsseoSpeed™ Profile 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

October 25, 2013

DENTSPLY Implants
C/O Linda K. Schulz, BSDH, RDH
PaxMed International, LLC
12264 El Camino Real, Suite 400
SAN DIEGO CA 92130

Re: K130999
Trade/Device Name: OsseoSpeed™ Profile EV
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 23, 2013
Received: September 24, 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 contact 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>. 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,

Mary S. Bunner -S

Kwame Ulmer M.S.
Acting Division 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: K130999

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The ATLANTIS™ Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS™ Abutment to the endosseous implant.

ATLANTIS™ Abutment, ATLANTIS™ Crown Abutment and ATLANTIS™ Conus Abutment are compatible with ASTRA TECH Implant System Profile EV.

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)

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Mary S. Runner -S
Susan Runner DDS, PA 2013.10.25 08:23:13
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