K080396

510(k) Summary

Astra Tech AB
OsseoSpeed™ Narrow

APR 30 2008

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 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:	OsseoSpeed™ Narrow
Common Name:	dental implant
Classification Regulations:	Implant, Endosseous, Root Form, Class II, 21CFR 872.3640: 21 CFR 872.3630
Product Code:	DZE; NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

OsseoSpeed™ Narrow is intended to be used to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. The device may be used equally well in a single-stage or two-stage surgical procedure. It is indicated for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one-stage surgical approach is applied, the implant

may be immediately loaded when good primary stability is achieved and the functional load is appropriate. The OsseoSpeed Narrow product line shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors.

The fluoride-modified surface, though having a fluoride ion level far below that needed for caries prevention in teeth, provides a favorable substrate for bone attachment and osseointegration. OsseoSpeed Narrow is especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective. Because initial stability may be difficult to obtain in Type IV bone, immediate loading of single tooth restorations may not be appropriate in such situations.

DEVICE DESCRIPTION

Osseospeed Narrow is a self tapping, threaded, root-form dental implant intended to support prosthetic devices in edentulous or partially edentulous patients to restore esthetics and chewing function. It is made from titanium with a micro-roughened and fluoride-modified surface, designated OsseoSpeed.

EQUIVALENCE TO MARKETED DEVICE

Astra Tech AB demonstrated that, for the purposes of FDA's regulation of medical devices, the OsseoSpeed™ Narrow is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2009

Astra Tech AB
C/O Mr. Floyd G. Larson
Regulatory Affairs
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K080396
Trade/Device Name: OsseoSpeed™ Narrow
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: February 12, 2008
Received: February 13, 2008

Dear Mr. Larson:

This letter corrects our substantially equivalent letter of April 30, 2008.

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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting 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): K080396

Device Name: OsseoSpeed™ Narrow

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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)

Susan Runner

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

510(k) Number: K080396