K063779

510(k) Summary

Astra Tech, Inc.
OsseoSpeed™ 4.0S – 6 mm

APR 27 2007

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Astra Tech, Inc. 890 Winter Street, Suite 310 Waltham, MA 02451 Telephone (800) 531-3481 Fax (781) 890-6808
Official Contact:	Scott A. Root
Representative/Consultant:	Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone (858) 792-1235 Fax (858) 792-1236 email: flarson@paxmed.com

DEVICE NAME

Classification Name:	Implant, Endosseous, Root Form
Trade/Proprietary Name:	OsseoSpeed 4.0S - 6 mm
Common Name:	dental implant

DEVICE CLASSIFICATION

Implant, Endosseous, Root-Form is classified as Class II (21 CFR 872.3640). The product code is DZE. This device is classified by the Dental Products Branch.

INTENDED USE

The OsseoSpeed™ 4.0S - 6 mm is intended to be used to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla where immediate implant stability may be obtained. 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 after implantation where immediate implant stability may be obtained.

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 4.0S - 6 mm 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

Design and Material

OsseoSpeed 4.0S - 6 mm is a 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, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the OsseoSpeed™ 4.0S - 6 mm 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

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

APR 27 2007

Re: K063779
Trade/Device Name: OsseoSpeed 4.0S – 6mm
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulation Class: II
Product Code: DZE
Dated: March 7, 2007
Received: March 9, 2007

Dear Mr. Larson:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Chiu Lin, Ph.D.
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): K063779

Device Name: OsseoSpeed™ 4.0S - 6 mm,
a component of the Astra Tech Implant System

Indications for Use:

The OsseoSpeed™ system is intended to be used to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla where immediate implant stability may be obtained. 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 after implantation where immediate implant stability may be obtained.

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 implants are 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. Immediate loading of single tooth restorations is not recommended for the OsseoSpeed™ 4.0S - 6 mm implant.

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

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