K053384

510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Astra Tech, Inc. 890 Winter Street, Suite 310 Waltham, MA 02451-1493 Telephone: 1 (800) 531-3481 FAX:1 (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: 1 (858) 792-1235 FAX: 1 (858) 792-1236

DEVICE NAME

Classification Names:	Implant, Dental, Root-Form
Trade/Proprietary Name:	Fixture MicroThread™ OsseoSpeed™, a component of the Astra Tech Implant System
Common Name:	Dental Implant

ESTABLISHMENT REGISTRATION NUMBER

Astra Tech, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 1222802. The owner/operator number for Astra Tech, Inc. is 9003608.

DEVICE CLASSIFICATION

FDA has classified endosseous dental implants as Class II devices (21 CFR 872.3640 according to revision 69 FR 26307, May 12, 2004). The product code for "Implant, Dental, Root-Form" is DZE. Endosseous dental implants and abutments are reviewed by the Dental Products Panel.

INTENDED USE

Fixture MicroThread™ OsseoSpeed™ 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.

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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. Fixture MicroThread OsseoSpeed 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

Fixture MicroThread OsseoSpeed is a threaded, root-formed dental implant intended for supporting prosthetic devices in edentulous or partially dentate patients to restore their esthetics and chewing function. Fixture MicroThread OsseoSpeed is made from titanium with a micro-roughened and fluoride-modified surface, designated OsseoSpeed.

The implant is available with a straight or tapered contour at the implant neck and comes in different diameters and lengths. The abutments are screw-retained.

EQUIVALENCE TO MARKETED PRODUCT

The components provided for in this submission are physically equivalent in material, design and surface characteristics to those previously cleared. This submission clarifies the intended use and indications for Fixture MicroThread Osseospeed.

Basis of substantial equivalence:

Fixture MicroThread OsseoSpeed in this application is substantially equivalent to the currently marketed Fixture OsseoSpeed in intended use, material, design and surface characteristics. The indication for use statement is substantially equivalent to TiUnite implant, another implant with a modified surface having properties claimed to facilitate bone deposition and healing.

The previously submitted data and additional pre-clinical and clinical data with Fixture MicroThread OsseoSpeed illustrate that the fluoride-modified surface promotes increased and more rapid bone formation compared to the TiOblast surface, as well as increased bone-to-implant strength early in the healing phase, which is also maintained over time. This improved early bone support allows safe and efficacious use in all situations and especially in situations with soft bone and whenever immediate installation and immediate and early loading protocols are applied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2006

Astra Tech, Incorporated
C/O Mr. Floyd G. Larson
Paxmed International, Limited Liability Company
11234 El Camino Real
Suite 200
San Diego, California 92130

Re: K053384
Trade/Device Name: Fixture MicroThread™ OsseoSpeed™
Regulation Number: 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE
Dated: March 14, 2006
Received: March 15, 2006

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.

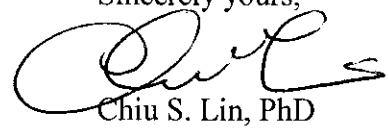
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu S. Lin, PhD
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): K053384

Device Name: Fixture MicroThread™ OsseoSpeed™,
a component of the Astra Tech Implant System

Indications for Use:

Fixture MicroThread™ OsseoSpeed™ 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.

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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)

Susan Runner

Concurrence of CDRH, Office of Device Evaluation (ODE)

General Hosp...
...ntal Devices

K053384