

JUN 25 1999

K991053

**510(k) SUMMARY**  
**Astra Tech Implants Dental System**  
**Additional Components –MicroMacro fixture**

Submitters Information

Astra Tech, Inc.  
430 Bedford Street, Suite 100  
Lexington, MA 02173  
781-861-7707  
Contact: Mr. Niklas Lidskog

Date Prepared

March 24, 1999

Name of Device

Astra Tech Implants - Dental System  
Additional component –MicroMacro fixture

Classification Name

Endosseous Implant

Predicate Devices

Similar Devices Previously Approved Under K931767 - Astra Tech Implants - Dental System

Description of Device and Intended Use

The additional fixture provided for by this 510(k) is added to the fixtures, abutments and other components necessary to meet various clinical situations in partially and totally edentulous patients. The implant is a root-form uncoated screw. It is cylindrical in shape. The coronal portion has a minute thread – microthread – and the apical part a magnified thread – Macrothread. It is made from commercially pure titanium. It has a defined surface texture achieved through titanium oxide grit blasting. The component is intended for use in selected fully edentulous and partially edentulous arches.

## List of Components

Fixture, MicroMacro, 3.5 mm x 8 mm	Part Number 22970
Fixture, MicroMacro, 3.5 mm x 9 mm	Part Number 22971
Fixture, MicroMacro, 3.5 mm x 11 mm	Part Number 22972
Fixture, MicroMacro, 3.5 mm x 13 mm	Part Number 22973
Fixture, MicroMacro, 3.5 mm x 15 mm	Part Number 22974
Fixture, MicroMacro, 3.5 mm x 17 mm	Part Number 22975
Fixture, MicroMacro, 3.5 mm x 19 mm	Part Number 22976
Fixture, MicroMacro, 4.0 mm x 8 mm	Part Number 22980
Fixture, MicroMacro, 4.0 mm x 9 mm	Part Number 22981
Fixture, MicroMacro, 4.0 mm x 11 mm	Part Number 22982
Fixture, MicroMacro, 4.0 mm x 13 mm	Part Number 22983
Fixture, MicroMacro, 4.0 mm x 15 mm	Part Number 22984
Fixture, MicroMacro, 4.0 mm x 17 mm	Part Number 22985
Fixture, MicroMacro, 4.0 mm x 19 mm	Part Number 22986



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 25 1999

Mr. Niklas Lidskog  
Astra Tech, Incorporated  
430 Bedford Street  
Suite 100  
Lexington, Massachusetts 02420

Re: K991053  
Trade Name: Astra Tech Implants - Dental System: New  
Fixtures MicroMacro Fixture  
Regulatory Class: III  
Product Code: DZE  
Dated: March 30, 1999  
Received: March 30, 1999

Dear Mr. Lidskog:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Lidskog

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

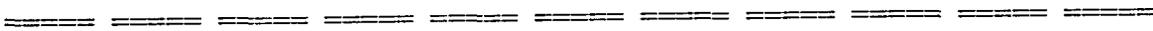
Enclosure

**510(k) Number (if known):** Not Known

**Device Name:** Astra Tech Implants – Dental System  
MicroMacro fixture

**Indications for Use:** For use in selected fully edentulous and partially edentulous arches

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)



Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Line X  
(Per 21 CFR 801.1091)

or

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-9G)

(Division Sign-Off) Pamela Scott for Susan Runner  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K991053