

1K974737

510(k) SUMMARY
Astra Tech Implants Dental System
Additional Components MAR 24 1998

Submitters Information

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

Date Prepared

December 16, 1997

Name of Device

Astra Tech Implants - Dental System
Additional Prosthetic and Laboratory Components - Fixture transfers and Fixture replicas

Classification Name

Endosseous Implant

Predicate Devices

Similar Devices Previously Approved Under K931767 - Astra Tech Implants - Dental System
Steri-Oss Dental Implants, Impression Coping, Open tray hex transfer, Implant Analog

Description of Device and Intended Use

The additional components provided for by this 510(k) are restorative components which will allow impression taking from the fixture level and fabrication of a stone cast with the fixture replicated in the correct position necessary to meet various clinical situations in partially and totally edentulous patients. The components are made of stainless steel. The indications and uses for these additional components are not different from similar components of the predicate device.

List of Components

Product	Diameter (mm)	Part Number
Replica	3.5	22398
Replica	4.0	22399
Replica ST	4.5	22509
Fixture Transfer	Short	22841
Fixture Transfer	Long	22842
Fixture Transfer ST	Short	22847
Fixture Transfer ST	Long	22848
Fixture Transfer PU	Short	22867
Fixture Transfer PU	Long	22868



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Niklas Lidskog
President
Astra Tech, Incorporated
430 Bedford Street, Suite 100
Lexington, Massachusetts 02173

MAR 24 1998

Re: K974737
Trade Name: Astra Tech Implant Dental System
Regulatory Class: III
Product Code: DZE
Dated: December 16, 1997
Received: December 19, 1997

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

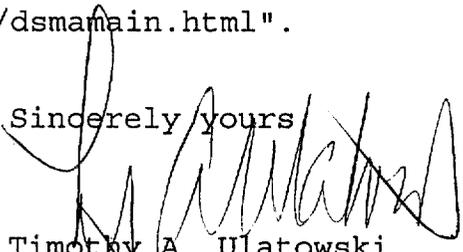
Page 2 - Mr. Lidskog

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

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/dsma/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): **K974737**

Device Name: **ASTRA TECH IMPLANTS – DENTAL SYSTEM**

Indications for Use:

For use in selected fully edentulous and partially edentulous arches.

The following table describes the indication for use for each component listed as part of this 510(k) submission:

Component	Part Number	Indication for Use
Replica 3.5	22398	Prosthetic component which can be embedded into a stone cast model which replicates the interior shape and exterior chamber and diameter of a fixture
Replica 4.0	22399	Prosthetic component which can be embedded into a stone cast model which replicates the interior shape and exterior chamber and diameter of a fixture
Replica ST 4.5	22509	Prosthetic component which can be embedded into a stone cast model which replicates the interior shape and exterior chamber and diameter of a fixture
Fixture Transfer - Short	22841	Single unit reseating type impression coping for accurate transfer of fixture location and angulation
Fixture Transfer – Long	22842	Single unit reseating type impression coping for accurate transfer of fixture location and angulation
Fixture Transfer ST – Short	22847	Two piece pick-up type impression coping for accurate transfer of fixture location and angulation
Fixture Transfer ST – Long	22848	Two piece pick-up type impression coping for accurate transfer of fixture location and angulation
Fixture Transfer PU – Short	22867	Multi-piece pick-up type impression coping for accurate transfer of fixture location and angulation
Fixture Transfer PU - Long	22868	Multi-piece pick-up type impression coping for accurate transfer of fixture location and angulation

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Line or Over-the-Counter Use

(Per 21 CFR 801.1091)

(Optional format 1-2-9G)

Sivan Punter

 (Division Sign-Off)
 Division of Device, Infection Control,
 and General Hospital Devices
 510(k) Number: K974737