

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

NOV 19 1998

Submitters Information

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

Date Prepared

December 16, 1997

Name of Device

Astra Tech Implants - Dental System
Prepable Abutment System - ADDITIONAL COMPONENTS for single-tooth and
multiple tooth constructions.

Classification Name

Endosseous Implant

Predicate Devices

Similar Devices Previously Approved Under K931767 - Astra Tech Implants - Dental
System (Abutment Screw ST, Healing Abutment, Angled Abutment Adapter)
Steri-Oss Dental Implants - Esthetic Abutment System, Steri-Oss Implants Friction
Drive Wrench, Try-In Kit

Description of Device and Intended Use

The Prepable Abutment System is comprised of a selection of components for
prosthetic and laboratory procedures for single-tooth and multiple tooth constructions.
The additional components provided for by this 510(k) are added to the fixtures,
abutments and other components necessary to meet various clinical situations in
partially and totally edentulous patients. All implants are made from commercially
pure titanium. The indications and uses for these additional components are not
different from similar components of the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1998

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

Re: K974738
Trade Name: Astra Tech Implants - Dental System
Regulatory Class: III
Product Code: DZE
Dated: September 22, 1998
Received: September 23, 1998

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.

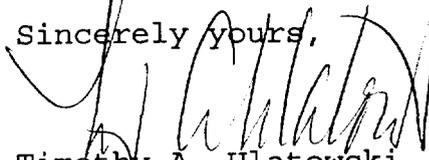
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 premarket 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): K974738

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
Profile UniAbutment 4.5	22852	Prepable component that is placed in fixture for cemented bridge construction
Profile UniAbutment 5.5 ultra	22855	Prepable component that is placed in fixture for cemented bridge construction
Profile UniAbutment 5.5	22856	Prepable component that is placed in fixture for cemented bridge construction
Profile UniAbutment 7.0	22860	Prepable component that is placed in fixture for cemented bridge construction
Profile BiAbutment 4.5	22782	Prepable component that is placed in fixture for cemented bridge construction
Profile BiAbutment 5.5 ultra	22785	Prepable component that is placed in fixture for cemented bridge construction
Profile BiAbutment 5.5	22786	Prepable component that is placed in fixture for cemented bridge construction
Profile BiAbutment 7.0	22790	Prepable component that is placed in fixture for cemented bridge construction
Profile BiAbutment ST 4.5	22870	Prepable component that is placed in fixture for cemented bridge construction
Profile BiAbutment ST 5.5	22872	Prepable component that is placed in fixture for cemented bridge construction
Profile BiAbutment ST 7.0	22874	Prepable component that is placed in fixture for cemented bridge construction
Abutment Screw ST, short	22554	Screw that is used to attach the Profile BiAbutment ST to the fixture

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Line (Per 21 CFR 801.1091) (Optional format 1-2-9G)

or Over-the-Counter Use

(Division Sign-Off) *Susan Doster*
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K974738