

K990304

JUL 15 1999

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

Submitters Information

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

Date Prepared

January 12, 1999

Name of Device

Astra Tech Implants - Dental System
Additional Abutments and Fixtures for Single Tooth Implant and Standard Implant

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 components provided for by this 510(k) added to the fixtures, abutments and other components necessary to meet various clinical situations in partially and totally edentulous patients. All implants are root-form uncoated screws and are made from commercially pure titanium. The indications and uses for these additional components are not different from similar components of the predicate device. The application also provides for the use of the Single Tooth Implant System in multiple construction clinical situations.

List of Components

Product	Diameter	Part Number
Uni Abutment	Ultrashort, 20 mm	22388
Uni Abutment	Ultrashort, 45 mm	22389
Healing Abutment ST	Short	22586
Healing Abutment ST	Intermediate	22589
Abutment Screw ST	Short	22554
Uni Abutment ST	20, 0.0 mm Cuff	22674
Uni Abutment ST	20, 1.5 mm Cuff	22675
Uni Abutment ST	20, 3.0 mm Cuff	22676
Uni Abutment ST	20, 4.5 mm Cuff	22677
Uni Abutment ST	20, 6.0 mm Cuff	22678
Uni Abutment ST	45, 0.0 mm Cuff	22694
Uni Abutment ST	45, 1.5 mm Cuff	22695
Uni Abutment ST	45, 3.0 mm Cuff	22696
Uni Abutment ST	45, 4.5 mm Cuff	22697
Uni Abutment ST	45, 6.0 mm Cuff	22698
Fixture ST	5.0 mm x 9 mm	22821
Fixture ST	5.0 mm x 11 mm	22822
Fixture ST	5.0 mm x 13 mm	22823
Fixture ST	5.0 mm x 15 mm	22824
Fixture ST	5.0 mm x 17 mm	22825
Fixture ST	5.0 mm x 19 mm	22826
Fixture ST	3.5/4.5, 9 mm	22209
Fixture ST	3.5/4.5, 9 mm	22212



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 1999

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

Re: K990304
Trade Name: Modification To Astra Tech Implants - Dental
System
Regulatory Class: III
Product Code: DZE
Dated: May 13, 1999
Received: May 17, 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.

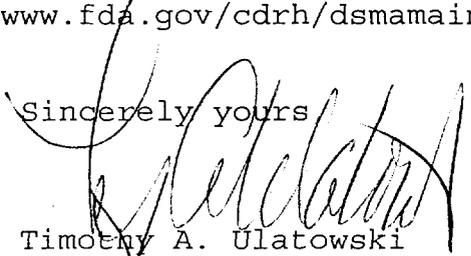
Page 2 - Mr. Lidskog

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.

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

