

NOV 19 2001

K012965

16. 510(k) Summary

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510(k) SUMMARY
Astra Tech Implants Dental System
Immediate Loading

Submitters Information

Submitter's Name: Astra Tech, Inc.

Submitter's Address: (US Representative)
430 Bedford Street, Suite 100
Lexington, MA 02420
781-861-7707

Contact's names and
telephone numbers: Niklas Lidskog, President, 781-861-7707
Ann-Mari Eriksson, M.S.Pharm., Manager Regulatory Affairs
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Bruce Manning, consultant, New England Biomedical
Research, 508-393-3100

Date Prepared: June, 2001

Address (Manufacturer) Astra Tech AB
P.O. Box 14
SE-431 21 Mölndal
Sweden

Name of Device

Astra Tech Implants - Dental System
Immediate Loading

Classification Name

Endosseous Implant

Predicate Devices

Brånemark system implant products, submitted by Nobel BioCare under 510(k)'s:
K992937, K993595.

Description of Device and Intended Use

This application provides for revision to the Dental Implant labeling allowing the
option of immediate loading of previously approved Astra Tech Implants – Dental

System after single stage surgical protocol.

The intended use for this device is for selected fully edentulous and partially edentulous arches using one or two stage surgical procedures.

The components are those previously approved to meet various clinical situations in partially and totally edentulous patients. All implants are threaded root-form screws made from commercially pure titanium. The indications and uses for the components are not different from similar components of the predicate device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Astra Tech, Incorporated
C/O Mr. Bruce R. Manning
President
New England Biomedical Research, Incorporated
96 West Main Street
Northborough, Massachusetts 01532

Re: K012965
Trade/Device Name: Astra Tech Implants-Dental System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implants
Regulatory Class: III
Product Code: DZE
Dated: July 25, 2001
Received: August 28, 2001

Dear Mr. Manning:

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.

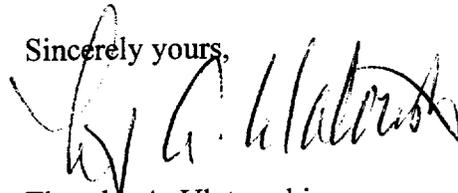
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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

Enclosure

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510(k) Number (if known): K01-2965

Device Name: Astra Tech Implants – Dental System

Indications for Use: This 510(k) requests new labeling for the System to describe conditions under which immediate loading of the device may be appropriate. Immediate loading could be applied in the anterior mandibular region (between the mental foramina) if at least four implants are splinted with a bar, or other continuous superstructure.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Line
(Per 21 CFR 801.1091)

or

Over-The-Counter Use

(Optional Format 1-2-9G)

Susan Pinney

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012965