NOV 7 2002

K023631

510K Summary of Safety and Effectiveness

Astra Tech Ceramic Abutment
October 28, 2002

1. Sponsor Name

   Astra Tech, INC.
   430 Bedford St, Suite 100
   Lexington, MA 02240

2. Device Name

   Proprietary Name: Astra Tech Implants – Dental System 'Ceramic Abutment'
   Common Name: Dental Implant
   Classification name: Endosseous Dental Implant (21 CFR 872.3640)

3. Identification of Legally Marketed Device

   - Astra Tech Implants – Dental System 'Prepable Abutment System' K974738
   - Nobel BioCare Ceradapt K number unknown
   - 3i ZiReal Post K991947

4. Device Description

   This 510k describes an additional component for the Astra Tech Implants – Dental System, the Ceramic Abutment.
   Ceramic Abutment 4.5/5.0 ST ø 5.5 mm

   The Ceramic Abutment is a transmucosal element that can be customized to meet high anatomical and esthetic demands. The Ceramic Abutment is designed to allow for individual solutions regarding function and esthetics. It is intended for cement-retained constructions and follows the same preparation principles as for regular crown and bridgework. The cement-retained superstructure excludes the need for non-esthetic screw entries through the crown. The design provides flexibility to mimic the anatomy of a natural tooth and to compensate for non-parallel fixtures. The esthetic properties of the Ceramic Abutment create a natural appearance of the soft tissue margin as well as a better result for the all-ceramic crown restoration. The Ceramic Abutment is ground and customized to its ideal shape using diamond wheels/burrs or silicone carbide stones. The Ceramic Abutment has a conical relation to the fixture which enables a tight and stable connection between the components. There is a

hexagonal interlock in relation to the fixture for antirotation and indexing. The Ceramic Abutment is connected to the fixture and tightened with the Abutment Screw ST/Long using a Hex screwdriver or Hex CA Driver.

5. Intended Use

The Ceramic Abutment is used with dental implant supported restorations in the anterior, canine, and premolar regions where high esthetic demands are expressed.

6 Comparison of Technological Characteristics

Substantial equivalence of the Ceramic Abutment is based on:

1. Design similarities between the proposed Ceramic Abutments and the currently marketed Prepable Abutment System
2. Performance testing. The proposed and currently marketed devices are very similar in terms of size, materials of construction, performance characteristics, and basic design.

The differences have no effects on the performance or safety of the Ceramic Abutments as evaluated in the performance testing. The same types of safety and effectiveness characteristics are raised with each of the devices.

In summary, the Ceramic Abutment described in this submission is, in our opinion, substantially equivalent to the predicate devices listed, which provide the same or similar functions, as well as design and technological characteristics. The intended use, statement of indications, technological characteristics and testing for the Ceramic Abutments support the concept of substantial equivalence.

7. Performance Testing

Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 7 2002

Astra Tech, Incorporated
C/O Mr. Bruce Manning
New England Biomedical Research, Incorporated
96 West Main Street
P.O. Box 809
Northborough, Massachusetts 01532

Re: K023631
Trade/Device Name: Astra Tech Implants – Dental System 'Ceramic Abutment'
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: NHA
Dated: October 28, 2002
Received: October 29, 2002

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 Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023631

Device Name: Astra Tech Implants – Dental System 'Ceramic Abutment'

Indications For Use:

The Ceramic Abutment is intended for customized prosthetic treatment.

The Ceramic Abutment is used with dental implant supported restorations in the anterior, canine, and premolar regions where high esthetic demands are expressed

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023631