MAY - 3 2001

K 001807

Advanced UroScience, Inc.

510(k) Summary

Submitter's Name, Address, and Date of Submission

Karen E. Peterson
Vice President of Regulatory, Clinical, & QA
Advanced UroScience, Inc.
1290 Hammond Road
St. Paul, MN 55110

Phone: 651-762-2146
Fax: 651-407-1975

Submitted: June 14, 2000

Device Name

Trade Name:	[Trade name] Tissue Marker
Classification Name:	Implantable Staple, 21 CFR 878.4750
Common/Usual Name:	Tissue Marker

Predicate Device

USSC, Auto Suture Site Marker staple (K983400)
Senorx Inc., Gel Mark Biopsy Site Marker (K000060)

Indication for Use

[Trade name] Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

Device Description

[Trade name] is a sterile, nonpyrogenic, single use tissue marker, which consists of non-absorbable pyrolytic carbon coated zirconium oxide beads that are clearly visible on standard radiographs as well as Magnetic Resonance Imaging (MRI), and ultrasound. [Trade name] is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location.

Technological Characteristics and Performance

The technological characteristics are similar to or equivalent to the predicate devices. Biocompatibility, bench, and animal testing have demonstrated that the device is safe and effective and that its performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2001

Ms. Karen E. Peterson
Vice President of Regulatory, Clinical
and Quality Affairs
Advanced UroScience, Inc.
1290 Hammond Road
St. Paul, Minnesota 55110

Re: K001807
Trade/Device Name: Tissue Marker
Regulation Number: 878.4750
Regulatory Class: II
Product Code: GDW
Dated: February 13, 2001
Received: February 14, 2001

Dear Ms. Peterson:

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 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). 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 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, 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.

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) 594-4659. 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 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K001807

Device Name **Tissue Marker**

Indications for Use

Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109

(Optimal Format 1-2-96)

DSMitchell TWB for CMW
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K001807