NOV - 5 1999

K993459

Advanced UroScience, Inc.

Attachment 4

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: 651-653-8512
Fax: 651-407-1975

Submitted: October 12, 1999

Device Name

Trade Name:	[trade name]
Classification Name:	Surgical Mesh, 21 CFR 878.3300
Common/Usual Name:	Surgical Mesh

Predicate Device

Brennen Biosynthetic Surgical Mesh Matrix (K982403)

Indication for Use

For use in the treatment of hernias where the connective tissue has ruptured or as a sling material to support the repositioning and support of the bladder neck for female urinary incontinence resulting from urethral hypermobility or sphincter deficiency.

Device Description

[Trade name] is a sterile, processed and treated porcine skin, which is intended for use in the reconstruction of soft tissue deficiencies.

Technological Characteristics and Performance

The technological characteristics are the same as or equivalent to the predicate device. Biocompatibility and bench testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Karen E. Peterson
Vice President, Regulatory, Clinical, and
Quality Affairs
Advanced UroScience, Inc.
1290 Hammond Road
SAINT PAUL MN 55110

SEP 28 2012

Re: K993459
Trade/Device Name: Surgical Mesh Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAG
Dated: October 12, 1999
Received: October 13, 1999

Dear Ms. Peterson:

This letter corrects our substantially equivalent letter of November 5, 1999.

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 (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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known) K993459

Device Name **Advanced UroScience [trade name]**
Surgical Mesh Matrix

Indications for Use

For use in the treatment of hernias where the connective tissue has ruptured or as a sling material to support the repositioning and support of the bladder neck for female urinary incontinence resulting from urethral hypermobility or sphincter deficiency.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109

OR

Over the Counter Use_____

(Optimal Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993459