DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 27 2015

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

Re: K002573
Trade/Device Name: Advanced UroScience Innersheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated (Date on orig SE ltr): August 17, 2000
Received (Date on orig SE ltr): August 18, 2000

Dear Ms. Peterson,

This letter corrects our substantially equivalent letter of November 16, 2000.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 -S

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

EXHIBIT 3

Indications for Use Statement

510(k) Number (if known) K 30 2573

Device Name **Advanced UroScience InnerSheath**

Indications for Use

Advanced UroScience InnerSheath is indicated for use to help position an injection needle within the center of an endoscope.

(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

(Optimal Format 1-2-96)

David A Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002573

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Advanced UroScience, Inc.

EXHIBIT 7

K002573

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: August 17, 2000

Device Name

Trade Name:	Advanced UroScience InnerSheath
Classification Name:	Endoscope and/or Accessories, 21 CFR 876.1500
Common/Usual Name:	Cannula

Predicate Device

Bard Stabilizing Cannula (K930827)

Indication for Use

Advanced UroScience InnerSheath is indicated for use to help position an injection needle within the center of an endoscope.

Device Description

Advanced UroScience InnerSheath consists of a cannula and a cap. The cannula is designed to fit easily within an endoscope and to permit easy alignment of an injection needle within the endoscope. The cap is designed to provide adequate gripping of the cannula and endoscope, and an adequate seal with the injection needle. Advanced UroScience InnerSheath is provided sterile and is intended for single use only.

Technological Characteristics and Performance

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