OCT 26 1998

16. **510(k) SUMMARY** K 982890 Pg 1 of 3

General Information

Date Prepared	August 14, 1998
Classification	Class II
Trade Name	Advanced UroScience Injection Needle
Common Name	Endoscopic Needle
Submitter	Advanced UroScience 1290 Hammond Road St. Paul, MN 55110 651-653-8512
Contact	Karen E. Peterson Vice President of Regulatory, Clinical, and Quality Affairs
Predicate Device	Single Wall Introducer Needle, Ocean Medical Products (K843719) Martech Endoscopic Injection Needle, Martech Medical Products, Inc (K960519)

Device Description

The Advanced UroScience Injection Needle consists of a stainless steel needle attached to a plastic luer lock hub. Needle length ranges up to 200 cm to accommodate the length of the endoscope channel and gauge ranges from 14 to 25. The needle length and gauge will be identified on the label. The luer lock hub, which is molded onto the needle, is designed to accommodate a standard syringe.

The Advanced UroScience Injection Needle is intended for use as an accessory for currently marketed endoscopes and provides delivery of injectable materials during an endoscopic procedure. The type of material to be injected is dependent on the nature of the procedure, but may include delivery of collagen during cystoscopic procedures, sclerosing agents during esophagoscopic and gastroscopic procedures, local anesthetics during cystoscopic or laryngoscopic procedures, or saline or contrast media during colonoscopic procedures.

The Advanced UroScience Injection Needle is provided sterile and is intended for single use only.

Indication

The Advanced UroScience Injection Needle is an accessory for currently marketed endoscopes to allow delivery of injectable materials into tissues during an endoscopic procedure.

Technological Characteristics

The Advanced UroScience Injection Needle consists of a stainless steel needle and luer lock connector hub where a standard syringe can be attached for injection of materials through the lumen of the needle into tissue. Multiple needle lengths are available to accommodate the length of the endoscope channel.

Summary

In summary Advanced UroScience believes the above listed predicate devices and the Advanced UroScience Injection Needle are substantially equivalent based on design, materials, methods of fabrication and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 1998

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

Re: K982890
Advanced UroScience Injection Needle
Dated: August 14, 1998
Received: August 17, 1998
Regulatory Class: II
21 CFR 876.1500/Procode: 78 FBK

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 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) 594-4613. 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" (21 CFR 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K982890

Device Name Advanced UroScience Injection Needle

Indications for Use

The Advanced UroScience Injection needle is an accessory for currently marketed endoscopes to allow delivery of injectable materials into tissues during an endoscopic procedure.

(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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982890

(Optimal Format 1-2-96)

indication