AUG 29 2005



K051905

## Section 8: 510(k) Summary

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| **Date Prepared** | July 13, 2005 |
| **New Device Name** | Uroplasty Rigid Endoscopic Needle |
| **Predicate Device** | Advanced UroScience Injection Needle (K982890) |
| **Contact** | Uroplasty, Inc.<br>2718 Summer Street NE<br>Minneapolis, MN 55413-2820<br>Telephone: (612) 378-1180, Facsimile: (612) 378-2027<br>info.usa@uroplasty.com |

**Intended Use**

The Uroplasty Rigid Endoscopic Needle is an accessory to currently marketed endoscopes allowing delivery of injectable material into tissues during an endoscopic procedure.

**Device Description**

The Uroplasty Rigid Endoscopic Needle is an accessory for endoscopes with a working channel inner diameter of 5 French or larger. The Rigid Endoscopic Needle is supplied sterile and is intended for single use only. The 5 French stainless steel cannula is 380 to 500 mm long with an 18-gauge tip (10 mm in length) and a metal luer lock connector; the needle also has a protective polyethylene sheath.

**Indication for Use**

The Uroplasty Rigid Endoscopic Needle is an accessory to currently marketed endoscopes allowing delivery of injectable material into tissues during an endoscopic procedure. The Uroplasty Rigid Endoscopic Needle may be used in a variety of endoscopic procedures for the delivery of a variety of injectable materials. The type of material to be injected will be dependent on the nature of the endoscopic procedure. Possible injectable materials include: tissue bulking agents; sclerosing agents; local anesthetics; saline; or contrast media.

**Technological Characteristics**

The new and predicate devices are technologically the same; they are both rigid endoscopic needles intended to be accessories for standard endoscopes for the use of administering injectable materials. Both devices have similar intended uses and principles of action; they are both supplied sterile and are for single use only. In the few instances where the devices differ, no concerns about safety or effectiveness are raised.

**Performance**

The Uroplasty Rigid Endoscopic Needle allows delivery of injectable materials into tissues during an endoscopic procedure, thereby achieving its intended use.

**Conclusion**

The subject device, the Uroplasty Rigid Endoscopic Needle, is substantially equivalent to the previously cleared endoscopic needle by Advance UroScience (K982890).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2005

Mr. Michael Morrell
Director of Regulatory Affairs
Uroplasty, Inc.
2718 Summer Street, NE
MINNEAPOLIS MN 55413-2820

Re: K051905
Trade/Device Name: Uroplasty Rigid Endoscopic Needle
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: July 13, 2005
Received: July 14, 2005

Dear Mr. Morrell:

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 (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 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

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| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# PREMARKET NOTIFICATION [510(k)] SUBMISSION
# UROPLASTY RIGID ENDOSCOPIC NEEDLE

## Indication for Use Statement

**510(k) Number:** K051905

**New Device Name:** Uroplasty Rigid Endoscopic Needle

**Indication for Use:** The Uroplasty Rigid Endoscopic Needle is an accessory to currently marketed endoscopes allowing delivery of injectable material into tissues during an endoscopic procedure. The Uroplasty Rigid Endoscopic Needle may be used in a variety of endoscopic procedures for the delivery of a variety of injectable materials. The type of material to be injected will be dependent on the nature of the endoscopic procedure. Possible injectable materials include: tissue bulking agents; sclerosing agents; local anesthetics; saline; or contrast media.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over the Counter Use _____

Nancy C Brogdon
(Division Sign-off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K051905