Uroplasty

Uroplasty, Inc.
5420 Feltl Road, Minnetonka, MN 55343 USA
Main: 952 426 6140 (tel), 952 426 6199 (fax)
Toll free: 866 258 2182 (tel), 866 255 4522

510(k) Summary

AUG 3 2012

Submitter	Uroplasty, Inc. 5420 Feltl Road Minnetonka, MN 55343 Telephone: (952) 426-6140, Fax: (952) 426-6199 Email: info.usa@uroplasty.com
Date Prepared	May 2, 2012
Contact	Emily Metcalfe, Regulatory Affairs Specialist Email: emily.metcalfe@uroplasty.com
Trade Name	Uroplasty Rigid Endoscopic Needles
Common Name	Endoscopic needles
Classification Name	Endoscopes and accessories (21 CFR 876.1500, Product Code FBK)
Legally Marketed (Predicate) Device	Uroplasty Rigid Endoscopic Needles (K091391)

Device Description

The Uroplasty Rigid Endoscopic Needle is an accessory for endoscopes with a working channel inner diameter of 4 French or larger. The Rigid Endoscopic Needle is supplied sterile and is intended for single use only. The Rigid Endoscopic Needle is comprised of a stainless steel cannula 300 – 500 mm in length with an 18-23 gauge tip (10 – 15 mm in length) and a copolyester Luer lock hub.

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. 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.

Comparison to Predicate Device

The Uroplasty Rigid Endoscopic Needles have the same intended use and same fundamental technology as the predicate device. Both feature a stainless steel needle cannula and tip with a Luer lock hub for attachment to syringes used during endoscopic procedures to deliver injectable materials to patient tissues. The Uroplasty Rigid Endoscopic Needles have a modified needle hub compared to the predicate device.

Summary of Non-Clinical and Performance Data

Uroplasty conducted biocompatibility and functional testing to support the substantial equivalence of the Uroplasty Rigid Endoscopic Needles to the predicate device. Functional tests included tests to demonstrate forces experienced by the needle during use and to demonstrate mechanical strength.

Conclusion

The Uroplasty Rigid Endoscopic Needle is substantially equivalent to the previously cleared endoscopic needle by Uroplasty (K091391).

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. Emily Metcalfe
Regulatory Affairs Specialist
Uroplasty, Inc.
5420 Feltl Road
MINNETONKA MN 55343

AUG 3 2012

Re: K121337
Trade/Device Name: Uroplasty Rigid Endoscopic Needles
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: July 13, 2012
Received: July 16, 2012

Dear Ms. Metcalfe:

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

Enclosure

Indications for Use Statement

510(k) Number: K121337

New Device Name: Uroplasty Rigid Endoscopic Needles

Indication for Use: The Uroplasty Rigid Endoscopic Needles are accessories to currently marketed endoscopes allowing delivery of injectable material into tissues during an endoscopic procedure. The Uroplasty Rigid Endoscopic Needles 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.

Prescription Use X (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121337