K091391

Section 5: 510(k) Summary

JUN 30 2009

Date Prepared	May 8, 2009
New Device Name	Uroplasty Rigid Endoscopic Needles
Predicate Device	Uroplasty Rigid Endoscopic Needle (K051905)
Contact	Uroplasty, Inc. 5420 Feltl Road Minnetonka, MN 55343 Telephone: (952) 426-6140, Facsimile: (952) 426-6199 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 4 French or larger. The Rigid Endoscopic Needle is supplied sterile and is intended for single use only. The stainless steel cannula is 300 to 500 mm long with an 18-23 gauge tip (10 – 15 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 Uroplasty (K051905).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2009

Mr. Michael Morrell, RAC
Director of Regulatory Affairs and Quality Assurance
Uroplasty, Inc.
5420 Feltl Road
MINNETONKA MN 55343-7982

Re: K091391
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: May 8, 2009
Received: May 11, 2009

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 (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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: K091391

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.

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, Abdominal,
and Radiological Devices
510(k) Number K091391