K110491

MAR 16 2011

510(k) Summary
Safety and Effectiveness Data Summary

Prepared By:	Pluromed, Inc. 25-H Olympia Avenue Woburn, MA 01801
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Contact Person:	James Wilkie jwilkie@pluromed.com
Date Prepared:	March 7, 2011
Proprietary Name:	BackStop Catheter
Common Name:	Urological Catheter
Classification Name:	Urological Catheters and Accessories
Substantial Equivalence:	BackStop Catheter 510(k) Number: K103349
Classification:	Class II
Regulation Number:	876.5130
Product Code:	KOD
Description of Device:	The BackStop Catheter is a 100cm, 3 French, single lumen catheter with a radiopaque tip that facilitates access to the urinary tract. The catheter is inserted over a guidewire or through the working channel of a ureteroscope and is advanced through the urinary tract to the desired location. Once in place, fluid may be injected via the catheter. The device is a single lumen catheter with a stainless steel braid and a standard female luer lock hub on the proximal end.
Intended Use:	The 3F BackStop Catheter is indicated for use by physicians for facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the injection of gels, such as BackStop™, or fluid into the urinary tract.
Substantial Equivalence:	The modified device is identical to, and has the same technological characteristics as the predicate device, except for some of the materials of construction and the method of sterilization.

Results of bench testing have established the device as safe and effective for its intended use, which is identical to that of the predicate device.

Non-Clinical Data:

Pluromed has conducted the following non-clinical performance tests, with samples accelerated aged at T=7 months, T=13 months and T=37 months, in support of the changes in materials and method of sterilization to the proposed BackStop Catheter.

- Catheter hub-to-shaft tensile strength
- Catheter pressure during gel delivery
- Catheter Burst/Leak Pressure
- Catheter Insertion Force
- Catheter Column Strength
- Shaft Tensile Strength
- Catheter Hub Testing

Conclusions: The results of the non-clinical performance tests demonstrate the equivalence of the modified BackStop Catheter to the predicate device. The proposed BackStop Catheter is considered safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. James Wilkie
Vice President, Operations
Pluromed, Inc.
25-H Olympia Avenue
WOBURN MA 01801

MAR 16 2011

Re: K110491
Trade/Device Name: BackStop Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KOD
Dated: February 16, 2011
Received: February 22, 2011

Dear Mr. Wilkie:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110491

Device Name: BackStop Catheter

Indications for Use:

The 3F BackStop Catheter is indicated for use by physicians for facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the injection of gels, such as BackStop™, or fluid into the urinary tract.

Prescription Use ✓ AND/OR Over the Counter Use ___

(21 CFR 801 Subpart D) (21 CFR 807 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 K110491