K090430
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510(k) Summary

Safety and Effectiveness Data Summary

Prepared By:	Pluromed, Inc. 25-H Olympia Avenue Woburn, MA 01801
Telephone Number:	781.932.0574
Fax Number:	419.828.6350
Contact Person:	James Wilkie
Proprietary Name:	BackStop™ and BackStop™ Injector (accessory to BackStop)
Classification Name:	Ureteral Stone Dislodger
Common Name:	Urological stone entrapment device
Classification:	Class II
Regulation Number:	21 CFR 876.4680
Product Code:	FFL
Performance Standards:	No Performance Standards have been established for the device described in this Premarket Notification under section 514 of the FD&C Act.
Predicates:	1. Cook Urological N-Trap™ (K863081) 2. Boston Scientific Stone Cone™ (K970121) 3. Boston Scientific Temporary Indwelling Ureteral Catheter / Ureteral Stent (K013784) 4. Boston Scientific Temp-Tip Drainage Catheter (K924608)
Description of Device:	BackStop™ is a self-forming polymeric plug with reverse thermosensitive properties. At room temperature it is viscous but injectable. When the temperature of the plug increases , its viscosity increases and it forms a plug that is intended for use in the ureter to prevent migration of renal calculi during intracorporeal lithotripsy procedures. The material is water soluble and is removed by irrigating the plug with saline.
Substantial Equivalence:	Below is a comparison of predicate devices to BackStop™.

	Pluromed BackStop™ current 510k	Cook Urological N-Trap™ 510(k) K863081	Boston Scientific Stone Cone™ 510(k) K970121	Boston Scientific Temporary Indwelling Ureteral Stent 510(k) K013784	Boston Scientific Temp-Tip drainage catheter 510(k) K924608
Intended Use	BackStop is intended for use in the ureter to prevent migration of renal calculi during intracorporeal lithotripsy procedures.	To prevent retrograde migration of stone fragments during lithotripsy	To entrap stone fragments during lithotripsy	To facilitate the passage of urine from the kidney to the bladder.	To facilitate drainage from the kidney to the bladder.
Mode of Action	Mechanically occludes the ureter. Stones or fragments are trapped by the plug.	Mechanically occludes the ureter. Stones or fragments are trapped in basket.	Mechanically occludes the ureter. Stones or fragments are trapped in cone.	Facilitates ureteral drainage	Facilitates ureteral drainage
Removal	Dissolved with saline, excreted	Manually removed	Manually removed	Dissolution and excretion in urine	Dissolution of PVA distal tip and excretion in urine
Application	Manual insertion into the ureter	Manual insertion into ureter	Manual insertion into ureter	Manual insertion into the ureter	Manual insertion into the ureter
Materials	Rapid Transition Polymer, saline	Nitinol	Nitinol	Reversible cross linked alginate polymer with incorporated radiopacifier	PVA distal tip
Shape	Gel plug takes the shape of the ureter	Round mesh basket with tether for removal from ureter	Conical tipped basket with tether for removal from ureter	Extended polymeric tube with open ended coil at each end	Pigtail shape
Stone Removal	Conventional stone removal	Physically captured in mesh basket and manually withdrawn	Physically captured in conical basket and manually withdrawn	N/A	N/A
How Supplied	Sterile package	Sterile package	Sterile package	Sterile package	Sterile package
Use	Single Use	Single Use	Single Use	Single Use	Single Use
Sterility	Sterile	Sterile	Sterile	Sterile	Sterile

Clinical Summary:

BackStop™ was evaluated in a prospective, randomized, single-blind, controlled multi-site clinical study. A total of sixty-eight (68) subjects with a single stone in the proximal ureter and an indication for ureteroscopic lithotripsy were enrolled and each subject was randomly assigned to either the experimental group (BackStop™, n=34) or the control group (standard of care, no anti-retropulsion device, n=34). Measured endpoints included the presence of retropulsion, the need for subsequent procedures, stone-free rate at follow-up, the occurrence of adverse events and the ability to dissolve BackStop™ and reverse the ureteral plug at the completion of lithotripsy. Results: There were no adverse events, nor any incidents of an occluded ureter post-lithotripsy in the BackStop™ group. The test of the primary study hypothesis revealed a statistically significant lower rate of retropulsion (p=0.0002) in the BackStop™ group (8.8%, n = 3) compared to the control group (52.9%, n = 18). There were no significant differences between the two groups with respect to the secondary efficacy endpoints of stone-free rate at follow-up or need for additional procedures. The investigators concluded that BackStop™ is a novel and easy to use method of preventing stone fragment retropulsion during lithotripsy for the management of ureteral stones. Pluromed feels the study supports the conclusion that BackStop™ is a safe and effective method of preventing retropulsion during lithotripsy. BackStop™ prevents retropulsion of all size fragments and is easily removed after the procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2009

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

Re: K090430
Trade/Device Name: BackStop™
Regulation Number: 21 CFR 876.4680
Regulation Name: Ureteral stone dislodger
Regulatory Class: II
Product Code: ONJ
Dated: May 7, 2009
Received: May 11, 2009

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 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.

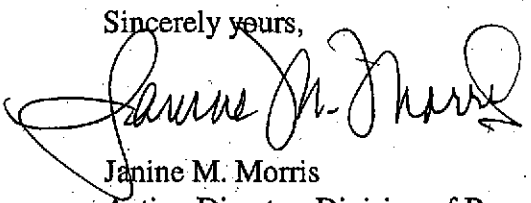
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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

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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

Indications for Use

510(k) Number (if known): K090430

Device Name: BackStop

Indications For Use: BackStop is intended for use in the ureter to prevent migration of renal calculi during intracorporeal lithotripsy procedures.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K090430