

MAR 19 2012

**510(k) SUMMARY K113854**

A summary of 510(k) safety and effectiveness information in accordance with 21CFR 807.92.

SUBMITTER INFORMATION	
Name	CareFusion
Address	1500 Waukegan Road MPWM, McGaw Park, IL 60085 USA
Phone number	(847) 473-7404
Fax number	(847) 473-7790
Establishment Registration Number	1423507
Name of contact person	Joy Greidanus
Date prepared	December 22, 2011
NAME OF DEVICE	
Trade or proprietary name	Pleurx Peritoneal Catheter System
Common or usual name	Catheter, peritoneal, long-term, indwelling
Classification name	Peritoneal dialysis system and accessories
Classification panel	Gastroenterology/Urology
Regulation	Class II per 21CFR §876.5630, Procode FJS
Product Code(s)	Multiple
Legally marketed device(s) to which equivalence is claimed	CareFusion Pleurx Peritoneal Catheter Kit and Drainage Kits: K051711 Bard Aspira Peritoneal Drainage System: K110396
Device description	The Pleurx Peritoneal Catheter System provides patients with a convenient method to relieve malignant ascites symptoms at home. The primary components of the Pleurx Catheter System are the Pleurx Peritoneal Catheter and the Pleurx Drainage Kits.



Intended use	<p>The Pleurx Peritoneal Catheter System is intended for intermittent, long term drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease, for the palliation of symptoms related to recurrent malignant ascites and for peritoneal placement only.</p> <p>The Pleurx Drainage Kits and Drainage Line Set are indicated for use with either the Pleurx Peritoneal Catheter or the Pleurx Pleural Catheter for intermittent drainage. The Drainage Line Kit is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle or other appropriate method.</p> <p>The Pleurx Drainage Bag is indicated for use only with the Pleurx Peritoneal Drainage Catheter for intermittent drainage.</p> <p>The Pleurx Dressing Kits are indicated for dressing of a catheter and exit site.</p> <p>The Pleurx Catheter Insertion Stylet is intended to aid in the percutaneous insertion of the Pleurx Catheter into the peritoneal space.</p>
--------------	--

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Characteristic	New Device	Predicates: CareFusion Pleurx Peritoneal Catheter Kit and Drainage Kits (K051711) Bard Aspira Peritoneal Catheter System (K110396)
Catheter Description	Internal: fenestrations, radiopaque markings & cuff External: valve	Same
Method	Percutaneously tunneled - indwelling	Same
Means of Drainage	Wall suction, water seal drainage system, portable suction, vacuum bottles or other appropriate method	Wall suction, water seal drainage system, vacuum bottles, syringe, drainage bag or other appropriate method



PERFORMANCE DATA	
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE	
Performance Test Summary	
Characteristic	Standard/Test/FDA Guidance
Biocompatibility	ISO 10993-1:2009 Biological evaluation of Medical Devices Part 1: Evaluation and Testing
Residuals	ISO 10993-7:2008 Biological evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals
Performance	EN 1617:1997 Sterile Drainage Catheters and Accessory Devices for Single Use
Performance	EN 1618:1997 Catheters Other Than Intravascular Catheters – Test Methods for Common Properties
Performance	ANSI/AAMI/ISO 11607-1,2:2006 Packaging for Terminally Sterilized Medical Devices
Performance	ISO 11138-1,2:2006 Sterilization of healthcare products - Biological Indicators
Performance	ISO 11737-1,2:2006 Sterilization of Medical Devices – Microbiological Methods Part 1 & 2
Performance	ISO 11135:2007 Medical Device, Validation and Routine Control of Ethylene Oxide Sterilization
Performance	ISO 594-1:1986 Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1: General Requirements
Performance	ISO 594-2:1998 Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock Fittings
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION	
N/A – No clinical tests were conducted for this submission	
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
The results of the non-clinical tests show that the CareFusion Pleurx Peritoneal Catheter System meets or exceed all performance requirements, and are substantially equivalent to the predicate devices.	



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Joy Greidanus
Regulatory Affairs Manager
Carefusion
1500 Waukegan Road
WAUKEGAN IL 60085

MAR 19 2012

Re: K113854
Trade/Device Name: Pleurx Peritoneal Catheter System
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FJS
Dated: December 22, 2011
Received: December 29, 2011

Dear Ms. Greidanus:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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); 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.

In addition, we have determined that your device kit contains Lidocaine and ChloroPrep, which are subject to regulation as drugs.

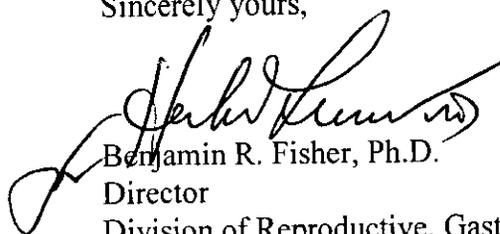
Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

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



1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.7404
FAX: 847.473.7790

Indication for Use

510(k) Number (if known): K113854

Device Name: Pleurx Peritoneal Catheter System

Indications for Use:

The Pleurx Peritoneal Catheter System is indicated for intermittent, long term drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease, for the palliation of symptoms related to recurrent malignant ascites and for peritoneal placement only.

The Pleurx Drainage Bottle Kits and Drainage Line Set are indicated for use either with the Pleurx Peritoneal Catheter or Pleurx Pleural Catheter for intermittent drainage. The Drainage Line Kit is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle or other appropriate method.

The Pleurx Drainage Bag Kit is indicated for use only with the Pleurx Peritoneal Catheter for intermittent drainage.

The Pleurx Dressing Kits are indicated for dressing of a catheter and exit site.

The Pleurx Catheter Insertion Stylet is intended to aid in the percutaneous insertion of the Pleurx Catheter into the peritoneal space.

Prescription Use (Per 21 CFR 801.109) or Over-The Counter Use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

A handwritten signature in black ink, appearing to read "Debra Lewis", is written over a horizontal line.

(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and
Urological Devices

510(k) Number K113854