



OCT 24 2012

### 510(k) SUMMARY K122422

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

<b>SUBMITTER INFORMATION</b>	
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	October 10, 2012
<b>NAME OF DEVICE</b>	
Trade or proprietary name	Pleurx Peritoneal Catheter System
Common or usual name	Catheter, peritoneal, long-term, indwelling
Classification name	Peritoneal Dialysis Systems 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 Catheter Systems: K113854 Bard Aspira Pleural Drainage System: K110396 Martech (MEDCOMP) Valved Tearaway Introducer: K090394 Greatbatch (MedAmicus) Incorporated FlowGuard Peelable Introducer: K040150
Reason for 510(k) submission	Expanding the indications for use and adding accessories.
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.



<p>Intended use of the device</p>	<p>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.</p> <p>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.</p> <p>The Pleurx Drainage Bag Kit is indicated for use only with the Pleurx Peritoneal 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 Access Kit is intended to provide access to the Pleurx Catheter for aspiration and catheter maintenance.</p> <p>The Pleurx Catheter Insertion Stylet is intended to aid in the percutaneous insertion of the Pleurx Catheter into the peritoneal space.</p> <p>The Valved Peelable Introducers are intended for use in the percutaneous insertion of a catheter into the peritoneal space.</p>
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**SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE**

Characteristic	New Device	Predicates: CareFusion Pleurx Catheter System: K113854 Bard Aspira Pleural Catheter System K110396 Martech (MEDCOMP) Valved Tearaway Introducer: K090394 Greatbatch (MedAmicus) Incorporated FlowGuard Peelable Introducer: K040150
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	Same
Valved Peelable Introducers	Peelable sheath, dilator, hub, valve	Same
Access Kit	Provides access for sample aspirations and catheter maintenance	Same
Insertion Stylet	Reduces fluid loss, provides stiffening	Same



<b>PERFORMANCE DATA</b>	
<b>SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE</b>	
Bench-level testing was carried out on the Pleurx Catheter System to demonstrate substantial equivalence. The performance testing requirements were determined by the predicate devices and further defined by the standards listed below. The testing conducted includes tensile strength, leakage, bond strength, deformation, security of connections, biocompatibility, aging, sterilization and residuals.	
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	ISO 11070 Sterile, Single-use Intravascular Catheters
Performance	ANSI/AAMI/ISO 11607-1,2:2006 Packaging for Terminally Sterilized Medical Devices
Performance	ASTM F1980-07 Accelerated Aging of Sterile Barrier Systems
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	AAMI TIR28:2009 Product Adoption and Process Equivalency for Ethylene Oxide Sterilization
<b>SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION</b>	
N/A – No clinical tests were conducted for this submission	
<b>CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA</b>	
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

OCT 24 2012

Ms. Joy Greidanus  
Regulatory Affairs Manager  
CareFusion  
1500 Waukegan Road  
MCGAW PARK IL 60085

Re: K122422  
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: August 8, 2012  
Received: August 9, 2012

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 Alcohol pads and Chloraprep applicator, 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:

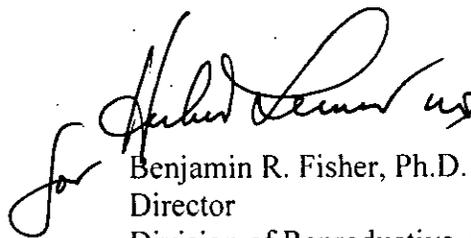
Director, Division of Drug Labeling Compliance (HFD-310)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857  
(301) 594-0101

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 (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 (240) 276-3150 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

K122422



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FAX: 847.473.7790

510(k) Number (if known): ~~Unknown at this time~~ K122422

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.

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The Valved Peelable Introducers are intended for use in the percutaneous insertion of a catheter into the peritoneal space.

Prescription Use  X  (Per 21 CFR 801 Subpart D)  
And/Or Over-The Counter Use \_\_\_\_\_ (Per 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number  K122422