



Food and Drug Administration
10903 New Hampshire Avenue
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November 3, 2016

CareFusion
Tamara Brey
Regulatory Affairs Advisor
75 North Fairway Drive
Vernon Hills, IL 60061

Re: K160437
Trade/Device Name: PleurX Peritoneal Catheter System
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: Class II
Product Code: PNG
Dated: October 3, 2016
Received: October 4, 2016

Dear Tamara Brey:

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. 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/tray. 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.

In addition, we have determined that your device kit contains Lidocaine and Chloraprep 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
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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)
K160437

Device Name
PleurX Peritoneal Catheter System

Indications for Use (Describe)

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, and for the palliation of symptoms related to recurrent malignant ascites.

The PleurX Lockable Drainage Line is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle or other appropriate method.

The PleurX Access Valve attaches only to the PleurX Catheter. The PleurX Valve Kit is intended to repair the PleurX Catheter and replace the PleurX Valve.

The PleurX LP Catheter Mini Kit is indicated for intermittent, long term drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease, and for the palliation of symptoms related to recurrent malignant ascites.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY - K160437

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

SUBMITTER INFORMATION	
Name	CareFusion
Address	75 North Fairway Drive, Vernon Hills, IL 60061 USA
Phone number	(847) 362-9485
Fax number	(312) 949-9245
Establishment Registration Number	1423507
Name of contact person	Tamara Brey
Date prepared	February 15, 2016
DESCRIPTION OF DEVICE	
Trade or proprietary name	PleurX Peritoneal Catheter System
Common or usual name	Peritoneal Catheter, peritoneal, long-term, indwelling
Classification name	Peritoneal dialysis system and accessories
Classification panel	Gastroenterology/Urology
Regulation	Class II per 21CFR §876.5630, Procode PNG
Product Code(s)	Multiple
Legally marketed device(s) to which equivalence is claimed	CareFusion PleurX Catheter System: K122422, and Bard Aspira Peritoneal Drainage System: K110396
Reason for 510(k) submission	This 510(k) submission is for a change in material formulation and concentration, and minor design modifications to the devices cleared under K122422.
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 of the device	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, and for the palliation of symptoms related to recurrent malignant ascites. The PleurX Lockable Drainage Line is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle or other appropriate method. The PleurX Access Valve attaches only to the PleurX Catheter. The PleurX Valve Kit is intended to repair the PleurX Catheter and replace the PleurX Valve. The PleurX LP Catheter Mini Kit is indicated for intermittent, long term drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease, and for the

	palliation of symptoms related to recurrent malignant ascites.	
SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	New Device	Predicate
Catheter Description	Internal: fenestrations, radiopaque markings & cuff External: valve	Same as predicate: CareFusion PleurX Catheter Systems: K122422
Method	Percutaneously tunneled - indwelling	Same as predicate: CareFusion PleurX Catheter Systems: K122422
Access Valve Description	Unique access tip, valved closed system to inject and withdraw fluids.	Same as predicate: Bard Aspira Drainage System: K110396
Materials of Construction	Silicone, Barium Sulfate, Polyester, Polyisoprene, Polypropylene, Colorant, ABS, Ink, Adhesive	Same as predicate: CareFusion PleurX Catheter Systems: K122422
CONCLUSION OF DEVICE COMPARISON		
The technological characteristics of the proposed devices are substantially equivalent to the predicates.		
PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
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 cuff adherence, tensile strength, leakage, imaging, flow rate, tissue ingrowth, biocompatibility, sterilization and EO residuals.		
Performance Test Summary		
Performance	BS EN 1617: 1997, Sterile Drainage Catheters and Accessory Devices for Single Use	
Performance	BS EN 1618: 1997, Catheters other than Intravascular Catheters – Test Methods for Common Properties	
Biocompatibility	ISO 10993-1: Part 1, Biological Evaluation of Medical Devices : Evaluation and Testing within a Risk Management Process.	
Biocompatibility	AAMI / ANSI / ISO 10993-5:2009/(R) 2014: Part 5, Biological Evaluation of Medical Devices -- Tests For In Vitro Cytotoxicity	
Biocompatibility	ISO 10993-06 Second Edition 2007-04-15: Part 6 Biological Evaluation Of Medical Devices - Tests For Local Effects After Implantation.	
Residuals	ISO 10993-7 Second Edition 2008-10-15: Part 7, Biological Evaluation Of Medical Devices - Ethylene Oxide Sterilization Residuals [Including: Technical Corrigendum 1 (2009)]	
Biocompatibility	ISO 10993-10 Third Edition 2010-08-01: Part 10, Biological Evaluation Of Medical Devices - Tests For Irritation And Skin Sensitization.	
Biocompatibility	ISO 10993-17:2002: Part 17, Biological evaluation of medical devices - Establishment of allowable limits for leachable substances	
Biocompatibility	ISO 10993-18:2005: Part 18, Biological evaluation of medical devices - Chemical characterization of materials	
Performance	ISO 11135 2nd Ed: Sterilization of Health-Care Products –Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization	

	Process for Medical Devices
Performance	ISO 11138-1 2nd Ed: Sterilization of Health Care Products - Biological Indicators - Part 1: General Requirements
Performance	ISO 11737-1 2nd Ed: Sterilization of Medical Devices – Microbiological Methods Part 1
Performance	AAMI TIR28:2009(R) 2013: Product Adoption and Process Equivalency for Ethylene Oxide Sterilization
Performance	AAMI / ANSI / ISO 11607-1:2006/(R)2010: Packaging For Terminally Sterilized Medical Devices - Part 1:Requirements For Materials, Sterile Barrier Systems And Packaging Systems [Including: Amendment 1 (2014)]
Performance	AAMI/ANSI/ISO 11607-2:2006/(R)2010: Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming, Sealing And Assembly Processes [Including: Amendment 1 (2014)]
Performance	ASTM F1980-07: Accelerated Aging of Sterile Barrier Systems
Performance	ISO 14630: Non-active Surgical Implants - General Requirements
Performance	ASTM F2052: Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment
Performance	ASTM F2119: Evaluation of MR Image Artifacts from Passive Implants
Performance	ASTM F2182: A Measurement of Radiofrequency Induced Heating on or Near Passive Implants During MRI
Performance	ASTM F2213: Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
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 is as safe, as effective, and performs as well as the legally marketed predicate devices.	