DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 31, 2016

CareFusion
Tamara Brey
Advisor, Regulatory Management
75 North Fairway Drive
Vernon Hills, Illinois 60061

Re: K160450
Trade/Device Name: Pleurx Pleural Catheter System
Regulation Number: 21 CFR 870.5050
Regulation Name: Patient Care Suction Apparatus
Regulatory Class: Class II
Product Code: DWM
Dated: September 26, 2016
Received: September 28, 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. 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 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160450

Device Name
Pleurx Pleural Catheter System

Indications for Use *(Describe)*

The PleurX Pleural Catheter Kits are indicated for intermittent, long term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The devices are indicated for 1) the palliation of dyspnea due to pleural effusion and 2) providing pleurodesis (resolution of the pleural effusion). The PleurX Pleural Catheter Kits are indicated for adults only.

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 Valve Kit is indicated for adults only.

The PleurX LP Catheter Mini Kit is indicated for intermittent, long term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The devices are indicated for the palliation of dyspnea due to pleural effusion and providing pleurodesis (resolution of the pleural effusion). The PleurX Low Profile Catheter is indicated for adults only.

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.

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510(k) SUMMARY K160450

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 Pleural Catheter System
Common or usual name	Pleural Drainage Catheter
Classification name	Patient Care Suction Apparatus
Classification panel	Anesthesiology
Regulation	Class II per 21CFR §870.5050, Procode DWM
Product Code(s)	Multiple
Legally marketed device(s) to which equivalence is claimed	CareFusion Pleurx Catheter System: K141965, and Bard Aspira Pleural Drainage System: K110409
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 K141965.
Device description	The Pleurx Pleural Catheter System provides patients with a convenient method to relieve pleural effusion symptoms at home. The primary components of the Pleurx Catheter System are the Pleurx Pleural Catheter and the Pleurx Drainage Kits.
Intended use of the device	The PleurX Pleural Catheter Kits are indicated for intermittent, long term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The devices are indicated for 1) the palliation of dyspnea due to pleural effusion and 2) providing pleurodesis (resolution of the pleural effusion). The PleurX Pleural Catheter Kits are indicated for adults only. 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 Valve Kit is indicated for adults only. The PleurX LP Catheter Mini Kit is indicated for intermittent, long term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The devices are indicated for the palliation of dyspnea due to pleural effusion and providing pleurodesis (resolution of the pleural effusion). The PleurX Low Profile Catheter is indicated for adults only.

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: K141965
Method	Percutaneously tunneled - indwelling	Same as predicate: CareFusion Pleurx Catheter Systems: K141965
Access Valve Description	Unique access tip, valved closed system to inject and withdraw fluids.	Same as predicate: Bard Aspira Drainage System: K110409
Materials of Construction	Silicone, Barium Sulfate, Polyester, Polyisoprene, Polypropylene, Colorant, ABS, Ink, Adhesive	Same as predicate: CareFusion Pleurx Catheter Systems: K141965

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

Performance Test Summary

Characteristic	Standard/Test/FDA Guidance
Biocompatibility	AAMI/ANSI/ISO 10993-1:2009 Biological evaluation of Medical Devices Part 1: Evaluation and Testing
Biocompatibility	AAMI/ANSI/ISO 10993-5: 2009 Biological Evaluation of Medical Devices – Part 5 Tests for In Vitro Cytotoxicity
Biocompatibility	AAMI/ANSI/ISO 10993-6: 2007 (R) 2010 Biological Evaluation of Medical Devices – Part 6 Tests for Local Effects After Implantation
Residuals	AAMI/ANSI/ISO 10993-7:2008 Biological evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals
Biocompatibility	AAMI/ANSI/ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10 Tests for Irritation and Skin Sensitivity
Biocompatibility	ISO 10993-17:2002 Biological evaluation of medical devices --Establishment of allowable limits for leachable substances
Biocompatibility	ISO 10993-18:2005 Biological evaluation of medical devices -- Chemical characterization of materials
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 11607-1:2006/(R)2010 Packaging for Terminally Sterilized Medical Devices- Part 1:Requirements For Materials, Sterile Barrier Systems And Packaging Systems [Including: Amendment 1 (2014)]
Performance	ANSI/AAMI/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 11138-1, 2nd Ed Sterilization of healthcare products - Biological Indicators - Part 1: General Requirements
Performance	ISO 11737-1 2nd Ed Sterilization of Medical Devices – Microbiological Methods Part 1
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	AAMI TIR28:2009(R)2013 Product Adoption and Process Equivalency for Ethylene Oxide Sterilization
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 Pleural Catheter System is as safe, as effective, and performs as well as the legally marketed predicate devices.	