October 21, 2020

CareFusion
Nazeer Khan
Manager, Regulatory Affairs
75 North Fairway Drive
Vernon Hills, Illinois 60061

Re: K201155
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: September 18, 2020
Received: September 21, 2020

Dear Nazeer Khan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. However, you are responsible to determine that the medical devices you use as components in the kits have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally 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 kits. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carolyn Y. Neuland, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201155

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 and non-malignant ascites that does not respond to medical management of the underlying disease and for the palliation of symptoms related to recurrent ascites. The use of the PleurX Peritoneal Catheter for non-malignant ascites is limited to patients who are intolerant or resistant to maximum medical therapy, refractory to large volume paracentesis (LVP) and are not candidates for a trans-jugular intrahepatic portosystemic shunt or LVP. The PleurX Peritoneal Catheter is 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.

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 – K

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
Phone number	(847) 362-8067
Establishment Registration Number	1423507
Name of contact person	Nazeer Khan
Date prepared	April 29, 2020
DEVICE INFORMATION	
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
Product Code(s)	PNG
Legally marketed device(s) to which equivalence is claimed	CareFusion PleurX Peritoneal Catheter System: K160437
Reason for 510(k) submission	This 510(k) submission is for a PleurX Peritoneal Catheter System for ascites management in patients with non-malignant as well as malignant causes.
Device description	The PleurX Peritoneal Catheter System provides patients with a convenient method to relieve ascites symptoms. The primary components of the PleurX Peritoneal Catheter System are the PleurX Peritoneal Catheter and the PleurX Drainage Kits.
Intended use of the device	The intended use of an indwelling peritoneal drainage catheter is for drainage of refractory ascites with long-term occurrence from the peritoneal cavity.
Indications for use	The PleurX Peritoneal Catheter System is indicated for intermittent, long term drainage of symptomatic, recurrent, malignant and non-malignant ascites that does not respond to medical management of the underlying disease and for the palliation of symptoms related to recurrent ascites. The use of the PleurX Peritoneal Catheter for non-malignant ascites is limited to patients who are intolerant or resistant to maximum medical therapy, refractory to large volume paracentesis (LVP) and are not candidates for a trans-jugular intrahepatic portosystemic shunt or LVP. The PleurX Peritoneal Catheter is 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.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	**New Device**	**Predicate**
Catheter Description	Same	CareFusion PleurX Peritoneal Catheter System: K160437 Internal: Fenestrations, radiopaque markings & cuff External: Valve
Method	Same	CareFusion PleurX Peritoneal Catheter System: K160437 Percutaneously tunneled indwelling
Means of Drainage	Same	Wall suction, water seal drainage system, portable suction, vacuum bottles or other appropriate method
CONCLUSION OF DEVICE COMPARISON		
The technological characteristics of the proposed device are substantially equivalent to the predicate.		
PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
Bench-level testing was carried out on the PleurX Peritoneal Catheter System to demonstrate substantial equivalence. The performance testing requirements were determined by the predicate devices and leak testing was performed to evaluate performance of the catheter valve.		
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION		
No clinical tests were conducted for this submission. The modified indications for use statement was supported using a clinical literature review. The literature review demonstrates that the device has a history of safety and efficacy in non-malignant refractory ascites and that the incidence of device-related complications is more closely related to patient specific health status and preferences than the underlying cause (malignant vs non-malignant) of ascites.		
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 device.		