November 2, 2017

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

Re: K170405
Trade/Device Name: BD Curve Ascites Shunt
Regulation Number: 21 CFR§ 876.5955
Regulation Name: Peritoneo-Venous Shunt
Regulatory Class: II
Product Code: KPM, DYB
Dated: September 29, 2017
Received: October 2, 2017

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 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 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. 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 (DICE) 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 (DICE) 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,

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

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)*
K170405

Device Name

BD Curve Ascites Shunt

Indications for Use *(Describe)*

Peritoneovenous shunting is indicated for patients with malignant or non-malignant intractable ascites (including patients with chylous ascites, hepatorenal syndrome, and idiopathic ascites), not responding to standard medical management, and not considered candidates for portal-venous shunting

The 17Fr valved peel-away introducer is intended for use in the percutaneous insertion of catheters in the peritoneal space.

The 15.5Fr Pigtail Revision Catheter is indicated for revising the peritoneal catheter of an BD Curve Ascites Shunt.

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.

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510(k) SUMMARY- K170405

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	November 1, 2017
DESCRIPTION OF DEVICE	
Trade or proprietary name	BD Curve Ascites Shunt
Device name	Ascites Shunt
Classification name	Peritoneo-Venous Shunt
Classification panel	Gastroenterology/Urology
Regulation	Class II per 21CFR §876.5955
Product Code(s)	KPM, DYB
Legally marketed device(s) to which equivalence is claimed	Denver Ascites Shunt And Percutaneous Access Kit With Ascites Shunt: K011862 Medcomp, Inc. – Valved Tearaway Introducer Generation II: K132498 CareFusion – Valved Peelable Introducers: K122422
Reason for 510(k) submission	This 510(k) submission is for minor design modifications to the Ascites Shunt pump chamber and the peritoneal catheter. A minor design modifications to the peritoneal revision catheter design and addition of a new placement accessory. Updates to labeling include a revision of placement techniques and updated patient selection considerations.
Device description	The Ascites Shunt is a fully implantable device that transfers fluid from the peritoneal space to the circulatory system to provide symptom relief for patients with malignant or non-malignant intractable ascites.
Intended use of the device	Peritoneovenous shunting is indicated for patients with malignant or non-malignant intractable ascites (including patients with chylous ascites, hepatorenal syndrome, and idiopathic ascites), not responding to standard medical management, and not considered candidates for portal-venous shunting. The 17Fr valved peel-away introducer is intended for use in the percutaneous insertion of catheters in the peritoneal space. The 15.5Fr Pigtail Revision Catheter is indicated for revising the peritoneal catheter of a BD Curve Ascites Shunt.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	**New Device**	**Predicates:** CareFusion Denver Ascites Shunt PAK: K011862 Medcomp, Inc. – Valved Tearaway Introducer Generation II: K132498 CareFusion – Valved Peelable Introducers: K122422
Ascites Shunt Overall Design	Shunt with pump chamber (Single Valved and Double Valved) with venous and peritoneal catheters	Same as predicate: CareFusion Denver Ascites Shunt PAK: K011862
Ascites Shunt Materials of Construction	Tubing: Silicone with a barium sulfate stripe and silique surface treatment. Pump Chamber Material: Silicone with silique surface treatment	Same as predicate: CareFusion Denver Ascites Shunt PAK: K011862
Ascites Shunt Placement Technique	Minimally invasive (Seldinger technique) for all shunts	Same as predicate: CareFusion Denver Ascites Shunt PAK: K011862
Ascites Shunt Design Intent	Placed percutaneously to manage ascites by recirculating ascitic fluid from the peritoneal space to the circulatory system	Same as predicate: CareFusion Denver Ascites Shunt PAK: K011862
Valved Peelable Introducer Overall Design	Peel-away introducer sheath which contains an integral valve seal and dilator comprised of a cylindrical tube with a locking hub	Same as predicate: Medcomp, Inc. – Valved Tearaway Introducer Generation II: K132498
Valved Peelable Introducer Design Intent	To obtain peritoneal access and facilitate catheter insertion while minimizing air/fluid leakage.	Same as predicate: CareFusion – Valved Peelable Introducers: K12242
Pigtail Revision Catheter Design Intent	Placed percutaneously to replace occluded peritoneal limb of Ascites shunt.	Same as predicate: CareFusion Denver Ascites Shunt PAK: K011862
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 Ascites Shunt to demonstrate substantial equivalence. The performance testing requirements were determined by the predicate devices and further defined by the standards listed below. The testing and evaluation conducted includes displacement volume, resealing capacity, interface testing, declogging, aging, biocompatibility, sterilization, and EO residuals.		
Performance Test Summary		

Biocompatibility	ISO 10993-1: Part 1, Biological Evaluation of Medical Devices: Evaluation and Testing within a Risk Management Process.
Biocompatibility	ISO 10993-5:2009/(R) 2014: Part 5, Biological Evaluation of Medical Devices -- Tests For In Vitro Cytotoxicity
Biocompatibility	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 10993-12, 2012 Biological Evaluation Of Medical Devices – Part 12: Sample Preparation and Reference Materials.
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
Sterilization	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
Sterilization	ISO 11138-1 2nd Ed: Sterilization of Health Care Products - Biological Indicators - Part 1: General Requirements
Sterilization	ISO 11737-1 2nd Ed: Sterilization of Medical Devices – Microbiological Methods Part 1
Sterilization	AAMI TIR28:2009(R) 2013: Product Adoption and Process Equivalency for Ethylene Oxide Sterilization
Sterilization	ANSI/AAMI ST72:2011: Bacterial endotoxins — Test methods, routine monitoring, and alternatives to batch testing
Packaging	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)]
Packaging	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)]
Risk Management	BS EN ISO 14971: 2012 Medical Devices. Application of Risk Management to Medical Devices.
Performance	EN ISO 14630: Non-active Surgical Implants - General Requirements
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
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 Ascites Shunt is as safe, as effective, and performs as well as the legally marketed predicate devices.	