FDA

Class 2 Device Recall ARROWgard Blue CVC Kit

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See Related Information[22]

Date Initiated by Firm	May 09, 2017
Create Date	June 12, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2337-2017
Recall Event ID	77232[23]
510(K)Number	K900263[24]
Product Classification	Catheter,intravascular,therapeutic,short-term less than 30 days[25] - **Product Code** FOZ[26]
Product	ARROWg+ard Blue CVC Kit The ARROWg+ard Blue CVCs are intended to permit venous access to the central circulation
Code Information	Material number: CDC-24301-1A, CDC-24306-1A Device Listing D025398
Recalling Firm/ Manufacturer	Arrow International Inc 2400 Bernville Rd Reading PA 19605-9607
For Additional Information Contact	610-378-0131
Manufacturer Reason for Recall	The Arrow CVC is indicated to provide short-term (<30 days) central venous access for treatment of diseases or conditions requiring central venous access including, but not limited to: -multiple infusions of fluids, medications, or chemotherapy -infusion of fluids that are hypertonic, hyperosmolar, or have divergent pH values -frequent blood sampling or blood/blood components infusions -infusion of incompatible medications -central venous pressure monitoring lack of usable peripheral IV sites -replacement of multiple peripheral sites for IV access
FDA Determined Cause [2]	Packaging
Action	Arrow International sent an Urgent Medical Device Recall Notification Letter dated May 11, 2017, to affected customers. The firm's notification letter is requesting that customers immediately assess their current inventory and to discontinue and quarantine any product with the specific lot codes listed in the letter. In addition, customers were asked to complete the Recall Acknowledgement form and fax or email it back to Customer Service so they can receive a Returns Good Authorization Number for the product's return. Customers with questions were instructed to contact their local sales representative or Customer Service at 1-866-246-6990.
Quantity in Commerce	27,485 units distributed in U.S., 4,371 units distributed internationally
Distribution	Worldwide Distribution - US (nationwide) and Canada
Total Product Life Cycle	TPLC Device Report[27]