Class 2 Device Recall ARROWgard Blue CVC Kit

Date Initiated by Firm: May 09, 2017
Create Date: June 12, 2017
Recall Status: Open, Classified
Recall Number: Z-2337-2017
Recall Event ID: 77232
510(K)Number: K900263
Product Classification: Catheter, intravascular, therapeutic, short-term less than 30 days - Product Code FOZ
Product: ARROWgard Blue CVC Kit
The ARROWgard 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: 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

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=155539
6/19/2017