Class 2 Device Recall ARROWgard Blue Plus MultiLumen CVC Kit

Date Initiated by Firm
Create Date
Recall Status
Recall Number
Recall Event ID
510(K)Number
Product Classification
Product
Code Information
Recalling Firm/ Manufacturer
For Additional Information Contact
Manufacturer Reason for Recall
FDA Determined Cause
Action

August 30, 2018
October 26, 2018
Open
Z-0282-2019
81117
K993691
Catheter, intravascular, therapeutic, short-term less than 30 days
Arrow AGB + Multi-Lumen CVC Kit, Cat. No. CDC-42703-B1A. Product Usage - The Arrow CVC is intended to provide short-term (< 30 days) central venous access for treatment of diseases or conditions requiring central venous access, including, but not limited to the following: Lack of usable peripheral IV sites, Central venous pressure monitoring, Total parenteral nutrition (TPN), Infusions of fluids, medications, or chemotherapy, and Frequent blood sampling or receiving blood transfusions/blood products.
23F16C0071
Arrow International Inc
2400 Bernville Rd
Reading PA 19605-9607
Customer Service
866-396-2111
The product was shipped after its expiry date due to a system error. The product lidstock identifies the correct expiration date however the accompanying purchase order shipping documentation identifies an incorrect expiration date. Per standard clinical practice the lidstock would most likely be checked prior to use and the product would not be used leading to a minor delay while a replacement is located. In the unlikely event that the product lidstock is not checked prior to use, there is potential for use of expired product, and product functionality or sterility cannot be guaranteed.
Under investigation by firm

On August 29, 2018, the firm notified customers via an Urgent Medical Device Recall letter. The letter informed customers of the product issue. Customers were advised to do the following: 1. If you have affected stock, immediately discontinue use and quarantine any products with the product code and lot number listed above, so that the affected products can be returned to Arrow. 2. To return product, complete the enclosed Recall Acknowledgement Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. This will allow us to document the amount of product you have on hand for return. A customer service representative will contact you with a Return Goods Authorization (RGA) Number and will provide instructions for the return of products to Arrow International. 3. If you have no affected stock, please complete the enclosed Recall Acknowledgement Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. This will allow us to document your receipt of this letter. If you have