FDA

Class 2 Device Recall ARROWgard Blue Plus MultiLumen CVC Kit

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See Related Information[22]

Date Initiated by Firm	August 30, 2018
Create Date	October 26, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0282-2019
Recall Event ID	81117[23]
510(K)Number	K993691[24]
Product Classification	Catheter, intravascular, therapeutic, short-term less than 30 days[25] - **Product Code** FOZ[26]
Product	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.
Code Information	23F16C0071
Recalling Firm/ Manufacturer	Arrow International Inc 2400 Bernville Rd Reading PA 19605-9607
For Additional Information Contact	Customer Service 866-396-2111
Manufacturer Reason for Recall	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.
FDA Determined Cause [2]	Under Investigation by firm
Action	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 Acknowledgment 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