Class 2 Device Recall Arrow CVC

See Related Information[22]

Date Initiated by Firm	November 14, 2018
Create Date	January 11, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-0723-2019
Recall Event ID	81665[23]
510(K)Number	K862056[24]
Product Classification	Catheter, percutaneous[25] - **Product Code** DQY[26]
Product	Arrow CVC 2 Lumen, Pediatric Two-Lumen Central Venous Cauterization Set with Blue FlexTip Catheter, 4 Fr 2 Lumen 5cm, Reference # CS-12402 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 " Frequent blood sampling or receiving blood transfusions/blood products
Code Information	Lots 14F18F0336 & 14F18E0121
Recalling Firm/ Manufacturer	Arrow International Inc 2400 Bernville Rd Reading PA 19605-9607
Manufacturer Reason for Recall	The lidstock states the incorrect priming volume and flow rates.
FDA Determined Cause [2]	Error in labeling
Action	The firm, Teleflex, sent an "Urgent Medical Device Notification" letter dated 11/13/2018 to its customers on 11/14/2018. The letter described the product, problem and action to be taken. The customers were instructed to do the following: 1. Place a copy of this notification with each unit of affected product currently in your inventory. 2. Using the provided customer letter template and acknowledgement form, communicate this notification to any of your customer who have received product included within the scope of this notification. 3. Have each of your customers who received the affected product return a completed acknowledgement form to you. 4. Once you have finished collecting and consolidating all of the acknowledgement forms from your customers and placing a copy of this notification with each unit of affected product in your inventory, please completed the enclosed Distributor Acknowledgement Form and fax it to 1-855-419-8507, Attn: Customer Service or email it to recalls@teleflex.com. This will

	allow us to document completion of this field action. If you have any other questions, feel free to contact your local sales representative or Customer Service at 1-866-396-2111.
Quantity in Commerce	15 in the US
Distribution	Worldwide distribution: US (nationwide) distribution to state of: FL and to countries of: Argentina, Canada, Chile, Columbia, Costa Rica, Dominican Republic, Ecuador, and Peru.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database 510(K)s with Product Code = DQY and Original Applicant = ARROW INTL., INC.[29]

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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=81665
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K862056
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DQY