Class 2 Device Recall Arrow VPS Access Kit

See Related Information 22

Date Initiated by Firm	April 28, 2017
Create Date	May 26, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2170-2017
Recall Event ID	77163[23]
510(K)Number	K103255[24]
Product Classification	Catheter, ultrasound, intravascular[25] - **Product Code** OBJ[26]
Product	Arrow(R) VPS(R) Access Kit for use with 4 and 5 Fr. Peripherally Inserted Central Venous Catheters
Code Information	ASK-04001-DU9 and ASK-04001-DU10, Device Listing Number D156491, Lot Numbers:, 23F15L0593, 23F16A0300, 23F16B0028, 23F16B0523, 23F16J0151, 23F16K0363, 23F16K0431, 23F16K0820, 23F15L0662, 23F16A0298, 23F16B0338, 23F16C0321, 23F16C0632, 23F16J0105, 23F16K0449
Recalling Firm/ Manufacturer	Arrow International Inc 2400 Bernville Rd Reading PA 19605-9607
For Additional Information Contact	610-378-0131
Manufacturer Reason for Recall	Arrow International is notifying each customer who received the affected that product that the kits do not contain important information regarding the 3M Tegaderm CHG Chlorhexidine Gluconate I.V. Securement Dressing.
FDA Determined Cause [2]	Unknown/Undetermined by firm
Action	Arrow International sent an Urgent Medical Device Notification letter dated May 2, 2017, to all affected customers to inform them of the issue. The letter will instruct the distributor to notify their customers if the product was further distributed and to return a completed acknowledgement form indicating the amount of units on hand. For further questions, please call (610) 378-0131.
Quantity in Commerce	3,918 units
Distribution	US Distribution to the state of : NC
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