Class 2 Device Recall ARROW HANDSOFF Infusion Port Thermodilution Catheter

See Related Information 22

Date Initiated by Firm	September 02, 2016
Create Date	November 02, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0331-2017
Recall Event ID	75372[23]
510(K)Number	K895268[24]
Product Classification	Catheter, intravascular, diagnostic[25] - **Product Code** DQO[26]
Product	HANDS-OFF Infusion Port Thermodilution Catheter consists of the Arrow IPTD thermodilution catheter enclosed in a contamination shield (Arrow Cath-Gard) with integral flushing/balloon test chamber, enabling the practitioner to prepare, test, and insert the catheter without exposing it to external contamination.
Code Information	Lot # 16F15C0114, 16F15D0003, 16F15A0072, 16F15F0031, 16F15F0090, 16F15H0037, 16F16B0001, 16F16B0014, 16F16C0056, 16F16C0079, 16F16C0109, 16F16E0004, 16F16E0030
Recalling Firm/ Manufacturer	Arrow International Inc 2400 Bernville Rd Reading PA 19605-9607
For Additional Information Contact	610-378-0131
Manufacturer Reason for Recall	Labeling inconsistency
FDA Determined Cause [2]	Labeling mix-ups
Action	Arrow sent an Urgent Medical Device Recall Notification letter dated September 20, 2016, to all affected customers via FedEx 2-day air. The letter identified the problem and provided instructions to immediately discontinue use and quarantine any products with the associated lot numbers indicated in the letter. If product was found, customers were asked to complete the Recall Acknowledgement Form and a Customer Service Rep will issue a Return Goods Authorization (RGA) Number for the product's return. Disposition of recalled product will be scrapped. For further questions, please call (610) 378-0131
Quantity in Commerce	330 units in US and 1,031 units OUS
Distribution	Nationwide distribution
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.