Class 2 Device Recall ARROW HANDSOFF Infusion Port Thermodilution Catheter

Date Initiated by Firm: September 02, 2016
Create Date: November 02, 2016
Recall Status: Open, Classified
Recall Number: Z-0331-2017
Recall Event ID: 75372
510(K)Number: K6695266
Product Classification: Catheter, intravascular, diagnostic - Product Code DQQ

Product: HANDSOFF 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.

Lot #: 16F15C0114, 16F15D0003, 16F15A0072, 16F15F0031, 16F15F0090, 16F15H0037, 16F16B0001, 16F16B0014, 16F16C0058, 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: 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

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=150156
11/21/2016