Class 2 Device Recall Custom Spinal Anesthesia Tray

See Related Information 22

Date Initiated by Firm	July 11, 2016
Create Date	November 01, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0327-2017
Recall Event ID	74879[23]
Product Classification	Tray, surgical[24] - **Product Code** LRP[25]
Product	Affected Pain Control Tray Component (5% Lidocaine Hydrochloride and 7.5% DExtrose Injection, USP) Injection of anesthetics to provide regional anesthesia
Code Information	Catalog Number: 560399 (Lot # 0061418559, 0061422389, 0061434523, 0061438084, 0061440188, 0061446168, 0061450971, 0061459227, 0061464239, Catalog Number: 560511 (Lot # 0061413435, 0061425996, 0061438393, 0061452272, 0061465310), Catalog # 560605 (0061420240, 0061429962, 0061442280, 0061449510, 0061460497, 0061471580), Catalog # 560631 (Lot# 0061438803), Catalog # 560632 (0061438818).
Recalling Firm/ Manufacturer	B. Braun Medical, Inc. 901 Marcon Blvd Allentown PA 18109-9512
For Additional Information Contact	Customer Support Department 800-227-2862
Manufacturer Reason for Recall	B. Braun Medical Inc. is voluntarily recalling specific lots of their Custom Spinal Anesthesia Tray which contains a drug component, 5% Lidocaine Hydrochloride and 7.5 % Dextrose Injection, USP that Hospira Inc. has recalled because the drug product does not meet the specification for color throughout shelf life.
FDA Determined Cause [2]	Under Investigation by firm
Action	The firm, B.Braun, mailed to customers a "VOLUNTARY DRUG RECALL NOTIFICATION" letter dated July 12, 2016. The letter described the product, problem and actions to be taken and to inform the customers of a drug recall issued by Hospira, Inc. The Customers were instructed to determine their current inventory of the affected lots Do not destroy any affected product), complete and return "Product Removal Acknowledgement" form via fax to: B.Braun Medical Inc., Quality Assurance department at (610) 849-1197 or email to PA_QualityAssurance.BBMUS_Service@bbraun.com within two weeks of receipt, even if you have no inventory. A BBMI Customer Service Representative will contact you to provide instructions for handling the affected product and arrange for return to BBMI. Should you have any questions or concerns regarding the attached information, please contact our Customer Support Department at (800) 227-2862.
Quantity in Commerce	1704 units
Distribution	US Distribution to: AL, IL, OK, MN, MA and WI.