FDA

Class 2 Device Recall Sterile IV Start Kit

See Related Information[22]

Date Initiated by Firm	July 29, 2016
Create Date	February 28, 2018
Recall Status[1]	*Completed*
Recall Number	Z-0691-2017
Recall Event ID	75291[23]
Product Classification	I.V. start kit[24] - **Product Code** LRS[25]
Product	Sterile IV Start Kits 50 units/trays per case Convenience kit for IV start procedures
Code Information	Lot Number 361105, exp date 1/01/2017, Product Catalog Number 375198
Recalling Firm/ Manufacturer	B. Braun Medical, Inc. 901 Marcon Blvd Allentown PA 18109-9512
Manufacturer Reason for Recall	Positive results from non-routine sterility testing commissioned by B. Braun Medical Inc. (BBMI) for the finished product of this lot.
FDA Determined Cause [2]	Unknown/Undetermined by firm
Action	BBMI (B. Braun) provided written notification on August 05, 2016, to all BBMI customers in receipt of the suspected product. These customers included both BBMI direct end customers and BBMI direct distributors. Customers were asked to determine if they had the affected lots in their possession. If they did, customers were asked not to destroy the product and to immediately discontinue use of and quarantine if found. Customers were also asked to complete the Product Removal Acknowledgement form and return to B. Braun. B. Braun will contact each customer if they have any full cases, partial cases or unused pieces of the affected products to provide instructions for handling and return of the affected products. Customers with questions were instructed to call 1-800-227-2862.
Quantity in Commerce	15,950 units
Distribution	Nationwide Distribution to GA, IL, and FL
Total Product Life Cycle	TPLC Device Report[26]

[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[27].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain