Class 2 Device Recall Sterile IV Start Kit

**Date Initiated by Firm**
July 29, 2016

**Create Date**
February 28, 2018

**Recall Status**
Completed

**Recall Number**
Z-0691-2017

**Recall Event ID**
75291

**Product Classification**
I.V. start kit - Product Code LRS

**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**
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

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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](#).

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

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Links on this page:


https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=149990

3/5/2018