Class 2 Device Recall Pain Management Tray

Date Initiated by Firm  
June 21, 2017

Create Date  
February 09, 2018

Recall Status  
Open, Classified

Recall Number  
Z-0575-2016

Recall Event ID  
7887823

Product Classification  
Needle, hypodermic, single lumen, Product Code FM  

Product  
Pain Management Tray, Product Catalog Number: 560602,

Local anesthesia of the skin prior to insertion of the regional anesthesia needle.

Code Information  
0061522622, 0061537909

Recalling Firm/Manufacturer  

B. Braun Medical, Inc.  
901 Marcon Blvd  
Allentown PA 18109-9512

For Additional Information Contact  
610-596-0500

Manufacturer Reason for Recall  
B. Braun Medical Inc. (BBMI) initiated this recall of various BBMI convenience kits containing the 22GA 1-1/2in SafetyGlide Needle due to the presence of loose polypropylene foreign matter was above release specification. This foreign matter has been identified as a product hub material which has been tested for biocompatibility per ISO 10993 during the product development process.

FDA Determined Cause  
Material/Component Contamination

Action  
The firm, BD, sent an "URGENT MEDICAL DEVICE RECALL" letter dated 6/12/2017 to its customers/kit packers. B Braun Medical Inc. (BBMI), sent a "VOLUNTARY MEDICAL DEVICE RECALL NOTIFICATION" letter dated 6/23/2017 to all BBMI customers in receipt of suspect product. Customers were notified by US Postal Service Certified Mail with registered return receipt mail or FedEx Priority. The letters described the product, problem and actions to be taken. The customers were instructed to review the device notification in its entirety and inform all users of the recall; determine your inventory of the affected product; Do not destroy any affected product; complete and return the "Product Removal Acknowledgement" form to B Braun Medical Inc. Quality Assurance department via fax to 610-849-1197 or email to PA_QualityAssurance.BBMUS_Service@bbraun.com within two 2 weeks of receipt, even if the total inventory in your possession is zero. and if you have any full cases, partial cases or unused individual pieces a BBMI Customer Support Representative will contact you to provide instructions for handling affected product and arrange for return. Should you have any questions or concerns regarding the recall, please contact our Customer Support Department at 800-227-2862.

Quantity in Commerce  
460 units

Distribution  
US Nationwide Distribution.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=160795  
2/19/2018