

FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Merit Custom Syringe Kit

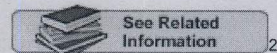


510(k)⁷|Registration & Listing⁸|Adverse Events⁹|Recalls¹⁰|PMA¹¹|Classification¹²|Standards¹³|Inspections¹⁴
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**Class 2 Recall
 Merit Custom Syringe Kit**



Date Posted	April 03, 2014
Recall Status¹	Open
Recall Number	Z-1320-2014
Recall Event ID	<u>67844</u> ²²
Premarket Notification 510(K) Number	<u>K875196</u> ²³
Product Classification	<u>Syringe, Piston</u> ²⁴ - Product Code <u>FMF</u> ²⁵
Product	Merit Custom Syringe Kit, Convenience Kit, I.R. Embolization Pack, K02-01010A, Sterile EO.
Code Information	Lot Number H574228
Recalling Firm/ Manufacturer	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, Utah 84095
For Additional Information Contact	Paul Kennedy 801-208-4301
Manufacturer Reason for Recall	The products are labeled as sterile but were not sterilized.
FDA Determined Cause²	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Release of Mat./Comp. prior to Test Results
Action	Merit Medical sent an Urgent Product Recall Notice dated March 14, 2014 to all customers and sales representatives via email. The letter identified the affected product, problem and actions to be taken. Customers were provided a Product Retrieval Form, product identification information, instruction to immediately quarantine any devices and discontinue use, ensure all personnel to whom devices were distributed are made aware of this field action, and instructions to contact their Merit representative to arrange product return and replacement. For questions call 1-801-316-4822.
Quantity in Commerce	15
Distribution	Worldwide Distribution - USA Nationwide in the state of WI and countries of Thailand and Hong Kong.
Total Product Life Cycle	<u>TPLC Device Report</u> ²⁶

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)²⁷

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

510(K) Database 510(K)s with Product Code = FMF and Original Applicant = MERIT MEDICAL SYSTEMS, INC.²⁸

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