Class 2 Device Recall Merit Custom Syringe Kit[6]

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Class 2 Recall Merit Custom Syringe Kit See Related Information[21]

Date Posted	April 03, 2014
Recall Status[1]	Open
Recall Number	Z-1320-2014
Recall Event ID	67844[22]
Premarket Notification 510(K) Number	K875196[23]
Product Classification	Syringe, Piston[24] - **Product Code** FMF[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 Cause [2]	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	TPLC Device Report[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]

Links on this page:

Class 2 Device Recall Pressure Monitoring Tubing

Class 2 Recall Pressure Monitoring Tubing

See Related Information[21]

Date Posted	April 03, 2014
Recall Status[1]	Open
Recall Number	Z-1319-2014
Recall Event ID	67844[22]
Premarket Notification 510(K) Number	K883718[23]
Product Classification	Display, Cathode-Ray Tube, Medical[24] - **Product Code** DXJ[25]
Product	Pressure Monitoring Tubing, PM6006. Pressure Monitoring Tubing (PM series) is used between the manifold and transducer as a conduit to transmit the fluid pressure of the patient to the pressure transducer.
Code Information	Lot Number H591335
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 Cause [2]	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	80
Distribution	Worldwide Distribution - USA Nationwide in the state of WI and countries of Thailand and Hong Kong.
Total Product Life Cycle	TPLC Device Report[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 = DXJ and Original Applicant = MERIT MEDICAL SYSTEMS, INC.[28]

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