Class 2 Device Recall Fluid Administration Sets

Date Initiated by Firm
August 12, 2016

Create Date
November 21, 2016

Recall Status
Open, Classified

Recall Number
Z-0649-2017

Recall Event ID
7501123

510(K)Number
K91667824

Product Classification
Set, administration, intravascular - Product Code FPA

Product
Custom Fluid Management Set, Sterile, EO, Rx Only

Used to transfer contrast media and saline from a container to a patients vascular system.

Code Information

Recalling Firm/Manufacturer
Merit Medical Systems, Inc.
1600 W Merit Pkwy
South Jordan UT 84095-2416

For Additional Information Contact
Luke Meidell
801-253-1600

Manufacturer Reason for Recall
Merit Medical Systems, Inc. announces a voluntary field action for Fluid Administration Sets due to mold in the drip chamber.

FDA Determined
Component design/selection