Class 2 Device Recall Fluid Administration Sets

See Related Information 22

Date Initiated by Firm	August 12, 2016
Create Date	November 21, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0649-2017
Recall Event ID	75011[23]
510(K)Number	K915678[24]
Product Classification	Set, administration, intravascular[25] - **Product Code** FPA[26]
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	Part Number: 701610001, K08-02053A, K08-02111A, K-08-2192A, K08-02385, K08-02385P, K08-02649, K08-02690, K08-02930a, K08-03044, K08T-02829, K09-00807AD, K09-01467AC, K09-01467AD, K09-01732N, K09-02334N, K09-02608A, K09-03491HP, K09-03586AC, K09-03743L, K09-04300Q, K09-04775HP, K09-04916JP, K09-05525A, K09-05648GP, K09-05993F, K09-07692D, K09-08374C, K09-08485F, K09-08556G, K09-08592N, K09-08603B, K09-08720G, K09-08720H, K09-08743L, K09-08743M, K09-08790C, K09-08813J, K09-09067C, K09-09144B, K09-09221CP, K09-09280A, K09-09326, K09-09418CP, K09-09439, K09-09474H, K09-09527D, K09-09657AP, K09-09672AP, K09-09677A, K09-09683I, K09-09683LP, K09-09859FP, K09-09966AP, K09-09966BP, K09-09983A, K09-10008C, K09-10009D, K09-10312, K09-10457C, K09-10590, K09-10593A, K09-10745BP, K09-10784A, K09-10800CP, K09-10870C, K09-10915F, K09-10947J, K09-10947LP, K09-10992CP, K09-11004F, K09-11004FP, K09-11132CP, K09-11132DP, K09-11137A, K09-11165B, K09-11259B, K09-11270A, K09-11303, K09-11303A, K09-11306, K09-11309D, K09-11336B, K09-11389, K09-11433F, K09-11452AP, K09-11530P, K09-11549D, K09-11655A, K09-11704, K09-11796C, K09-11796CP, K09-11867AP, K09-11901B, K09-11912, K09-11923C, K09-11940AP, K09-11971B, K09-12000, K09-12000A, K09-12006, K09-12065CP, K09-12065D, K09-12065DP, K09-12123A, K09-12138, K09-12138A, K09-12138B, K09-12216, K09-12276, K09-12304, K09-12305, K09-12356, K09-12376, K09-12393, K09-12408, K09-12408A, K09-12421, K09-12431, K09-12529, K09-12530, K09-12530P, K09-12562P, K09-12610, K09-12610P, K09-12647, K09-12689, K09-12698, K09T-03491C, K09T-09672G, K09T-10728C, K09T-11022C, K09T-11410C, K09T-11796C, K09T-11796D, K09T-11940A, K09T-12624, K10-05097A, K11-01028, K11-01376, K12T-06138A, K12T-07389A, and K12T-08215.
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