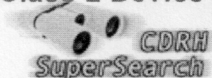


FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

**Class 2 Device Recall Fluid Administration Sets**

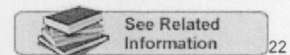


6 510(k) | DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup> | PMA<sup>12</sup> | HDE<sup>13</sup> | Classification<sup>14</sup> | Standards<sup>15</sup> | CFR Title 21<sup>16</sup> | Radiation-Emitting Products<sup>17</sup> | X-Ray Assembler<sup>18</sup> | Medsun Reports<sup>19</sup> | CLIA<sup>20</sup> | TPLC<sup>21</sup>

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**Class 2 Device Recall Fluid Administration Sets**



**Date Initiated by Firm** August 12, 2016  
**Create Date** November 21, 2016  
**Recall Status<sup>1</sup>** Open<sup>3</sup>, Classified  
**Recall Number** Z-0649-2017  
**Recall Event ID** 75011<sup>23</sup>  
**510(K)Number** K915678<sup>24</sup>  
**Product Classification** Set, administration, intravascular<sup>25</sup> - **Product Code** FPA<sup>26</sup>  
**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