Class 2 Device Recall Maquet Cardiopulmonary (MCP)/Getinge HLS Set Advanced

See Related Information[22]

Class 2 Device Recall Maquet Cardiopulmonary (MCP)/Getinge HLS Set Advanced

Date Initiated by Firm	July 11, 2019
Create Date	September 13, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-2149-2019
Recall Event ID	83336[23]
510(K)Number	K112360[24]
Product Classification	Oxygenator, cardiopulmonary bypass[25] - **Product Code** DTZ[26]
Product	Maquet Cardiopulmonary (MCP)/Getinge HLS Set Advanced 7.0. Model Number BEQ-HLS-7050 USA, Part Number 701052794
Code Information	Lot 70131093; UDI 04037691741543
Recalling Firm/ Manufacturer	Maquet Cardiovascular Us Sales, Llc 45 Barbour Pond Dr Wayne NJ 07470-2094
For Additional Information Contact	Maryanna Krivak 973-709-7483
Manufacturer Reason for Recall	The sets are configured with quick connectors that have been assembled in reverse on the arterial and venous lines, resulting in blue (venous) to red (arterial) and red (arterial) to blue

	(venous) connections. Due to this incorrect assembly, the sets cannot be primed from the reservoir prior to use, and the device may not function as intended.
FDA Determined Cause [2]	Under Investigation by firm
Action	Urgent Medical Device Recall - Removal notification letters dated 7/11/19 were sent to customers.
Quantity in Commerce	54
Distribution	The products were distributed to the following US states: AR, CA, FL, GA, IA, IL, IN, KY, NC, NE, NM, NV, NY, OH, OR, TN, and WI.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

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

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database	510(K)s with Product Code = DTZ and Original Applicant = MAQUET CARDIOPULMONARY AG[29]

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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=83336
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K112360
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DTZ
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DTZ
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=DTZ
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?
    start_search=1&productcode=DTZ&knumber=&applicant=MAQUET%20CARDIOPULMONARY%20AG

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=83336
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