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: Open, Classified
Recall Number: Z-2149-2019
Recall Event ID: 83336
510(K) Number: K112360

Product Classification: Oxygenator, cardiopulmonary bypass - Product Code DTZ

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** 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](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=174814)

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](https://www.fda.gov/MedicalDevices/default.htm).

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

Links on this page:
3. https://www.fda.gov/
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm