Class 2 Recall Maquet CARDIOSAVE

See Related Information[23]

Date Posted	February 23, 2015
Recall Status[1]	Open
Recall Number	Z-1140-2015
Recall Event ID	70510[24]
Premarket Notification 510(K) Number	K112372[25]
Product Classification	System, Balloon, Intra-Aortic And Control[26] - **Product Code** DSP[27]
Product	Maquet CARDIOSAVE Hybrid Intra-Aortic Balloon Pump (IABP)
Code Information	0998-00-0800-31 0998-UC-0800-31 0998-00-0800-32 0998-UC-0800-33 0998-00-0800-33 0998-UC-0800-52 0998-00-0800-34 0998-UC-0800-53 0998-00-0800-35 0998-UC-0800-55 0998-00-0800-45 0998-00-0800-52 0998-00-0800-53 0998-00-0800-55. CARDIOSAVE Hybrid IABPs serviced with a new/replacement power supply after August 19, 2014 are not affected.
Recalling Firm/ Manufacturer	Maquet Datascope Corp - Cardiac Assist Division 1300 MacArthur Blvd. Mahwah, New Jersey 07430-2052
Manufacturer Reason for Recall	Power supply malfunction complaints related to suboptimal thermal management.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Maquet Inc. sent a recall letter/return response form dated 1/30/2015.
Quantity in Commerce	1,300 units
Distribution	US Nationwide distribution
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = DSP and Original Applicant = CARDIAC ASSIST, MAQUET CARDIOVASCULAR LLC[30]

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