



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Cardiac Assist Recalls Lifesparc Controller and Accessories Kit for Software Update to Address Freezing and Crashing

Recall Date	Product Description	Recalling Firm	Recall Reason
1/25/2023	Lifesparc Controller SHIP KIT, LIFESPARC, CONTROLLER AND ACCESSORIES - 5900-0000; SHIP KIT, LIFESPARC, CONTROLLER ONLY - 5900-0001. Component of LifeSPARC System, used to pump the blood through an extracorporeal circuit.	Cardiac Assist, Inc Pittsburgh, Pennsylvania	A software update (v1.1.5) has been developed to address the issue of Critical Failure which can occur on the LifeSPARC Controller. The Critical Failure was first addressed in the firm's recall initiated July 21, 2022. During the Critical Failure, the software freezes or crashes and the screen does not display data.

Recall Class	Product Identification	Distribution	Affected Dates
I	Model No. 5900-0000 - UDI/DI 00814112020562 Model No. 5900-0001 - UDI/DI 00814112020623 Serial Numbers C00115 - C50295	Nationwide	December 2022 and prior

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