State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Maquet Medical Recalls CARDIOHELP for Low Blood Flow

Recall Date	Product Description	Recalling Firm	Recall Reason
12/13/2023	**Cardiohelp Emergency Drive** Part Numbers 701048002 and 701076205. The CARDIO HELP System is a blood oxygenation and carbon dioxide removal system.	**Maquet Medical Systems USA** Wayne, New Jersey	Product removal due to possible blocking or impairment of the CARDIOHELP Emergency Drive. This issue can lead to the patient being exposed to inappropriate low blood flow. Potential associated harms are ischemia and hypoxia.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Cardiohelp Emergency Drive** Part No. 701048002: UDI - 04037691643526; Serial Numbers 90425259 to 90425748 (Excluding 90425438, 90425443, 90425568, 90425570, 90425588, 90425716) Part No. 701076205: No UDI; Serial Numbers 90425438 to 90425748	1847 Units Nationwide	December 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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