State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

GE Medical Systems Information Technologies Recalls Prucka 3 Amplifiers For Increase In Temperature And Powering Off

Recall Date	Product Description	Recalling Firm	Recall Reason
9/27/2023	**Prucka 3 Amplifiers** Model P1801PA, and Field Replaceable Units (FRUs), Model 5875569, used with CardioLab AltiX and ComboLab AltiX	**GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES INC** Wauwatosa, Wisconsin	A diode on the power supply of the Prucka 3 Amplifier used with CardioLab/ComboLab systems could reach elevated temperatures and fail, then power off and become inoperable.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Prucka 3 Amplifiers** GTIN 00195278507044 (CardioLab) and 00195278507051 (ComboLab) Serial numbers for Amplifiers: SVS22330007SA, SVS22330008SA, SVS22330009SA, SVS22330010SA, SVS22330011SA, SVS22330012SA, SVS22330013SA, SVS22330014SA, …	81 Units Nationwide including California	8 August 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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