State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

B. Braun Medical Recalls Infusomat Large Volume Pump For Misalarm Of Upstream Occulsion

Recall Date	Product Description	Recalling Firm	Recall Reason
11/1/2023	**Infusomat Large Volume Pump** 8713051U, Wireless; Volumetric Infusion Pump System	**B. BRAUN MEDICAL, INC.** Allentown, Pennsylvania	Upstream occlusion alarm may sound when no occlusion exists, and the device will stop pumping. Interruption to the infusion of high-risk medications may lead to hemodynamic instability requiring medical intervention to prevent permanent impairment to body structures or body functions. In some cases, this may be life-threatening or may lead to death.
11/1/2023	**Infusomat Large Volume Pump** 8713052U, Non-Wireless BATTERY PACK; Volumetric Infusion Pump System	**B. BRAUN MEDICAL, INC.** Allentown, Pennsylvania	Upstream occlusion alarm may sound when no occlusion exists, and the device will stop pumping. Interruption to the infusion of high-risk medications may lead to hemodynamic instability requiring medical intervention to prevent permanent impairment to body structures or body functions. In some cases, this may be

			life-threatening or may lead to death.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Infusomat Large Volume Pump** UDI-DI: 04046964660887 Serial Numbers: 868497 -892669	9771 Units Nationwide	21 September, 2023 and prior
I	**Infusomat Large Volume Pump** UDI-DI: 04046964708626 Serial Numbers: 878498 -881897	884 Units Nationwide	21 September, 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE