State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Fresenius Kabi Usa, Llc Recalls Ivenix Infusion System (Iis), Lvp Software

Recall Date	Product Description	Recalling Firm	Recall Reason
10/2/2024	**Ivenix Infusion System (Iis), Lvp Software** LVP Software; LVP-SW-0004, Software Version 5.9.1 and prior. Infusion pump software for infusion management system.	**FRESENIUS KABI USA, LLC** North Andover, Ma	The software has anomalies that have the potential to cause alarms, nonfunctioning pump, or unresponsive screen while continuing therapy. These could cause serious patient harm or death.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Ivenix Infusion System (Iis), Lvp Software** UDI-DI: 00811505030122; Software Version 5.9.1 and prior	17 Units Nationwide	October 2024 and prior

For additional information, please visit the FDA website.

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