California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Fresenius Kabi USA, LLC Ivenix Infusion System (IIS), LVP Software LVP-SW-0005

Recall Date	Product Description	Recalling Firm	Recall Reason
02/04/2025	Ivenix Infusion System (IIS), LVP Software LVP-SW-0005. Indicated for use in a hospital and in outpatient care environments for the controlled administration of fluids through clinically accepted routes of administration.	Fresenius Kabi USA, LLC	Large Volume Pump Software, version 5.9.2 and earlier has potential for the following anomalies: The pump may become nonfunctional if during an alarm condition the Pause Audio option is repeated 70 time or more. If a secondary infusion is started at the exact moment a primary infusion completes and VTBI reaches 0, it will switch to primary. The primary infusion will infuse at the previously programed primary rate and continue until the infusion is stopped or the bag is empty.

Recall Class	Product Identification	Distribution	Affected Dates
I	UDI-DI: 00811505030122 Software 5.9.2 and prior	23 systems across CA, CO, GA, ID, MI, MS, NE, NJ, NV, OK, TX, UT, VA, WA, WI	January and prior

For additional information, please visit the FDA Website.