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 Recalls Lvp Software For Resolved Alarm Issue

Recall Date	Product Description	Recalling Firm	Recall Reason
3/20/2024	**LVP Software Of The Ivenix Infusion System (IIS)** LVP-SW-0004	**FRESENIUS KABI USA, LLC** North Andover, Massachusetts	Retroactively reported corrections from 2023: 1) A software defect may cause an incorrect (Fail-Stop) alarm when an adminis-tration set is loaded or coupled while the pump is executing the power-up se-quence. May lead to delay in therapy. 2) Alert is not annun-ciated informing the clinician that the bolus cannot be delivered when the entered bolus dose exceeds the Care Profile Hard Rate Max limit and Rapid Bolus is selected. May lead to over infusion. Both issues were resolved in all fielded product in software version 5.8.0, which was installed in affected units May thru August 2023.

Recall Class	Product Identification	Distribution	Affected Dates
II	**LVP Software Of The Ivenix Infusion System (IIS)** UDI-DI 00811505030122 Software versions 5.2.1/5.2.2	200 Units Nationwide California	May through August, 2023

For additional information, please visit the FDA website