# California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Fresenius Kabi USA, LLC – Ivenix Infusion System (IIS) Recall

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|---|---|---|---|
| 12/16/2025 | Ivenix Infusion System (IIS), LVP Software LVP-SW-0005, a software-controlled infusion pump system used for administering fluids to patients. | Fresenius Kabi USA, LLC<br><br>North Andover, MA, USA | Software version 5.10.1 and earlier contain anomalies that may lead to serious patient harm or death. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|---|---|---|---|
| I | **Lot Code:** N/A<br>**Model No.:** LVP-SW-0005 Software Versions 5.10.1 and prior<br>**UDI:** 00811505030122<br>**S/N range:** Not specified. | 30 Units; Nationwide Including California | November 2025 and prior. |

For additional information, please visit the FDA Website.