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 Ivenix Infusion System For Fluid Ingress

Recall Date	Product Description	Recalling Firm	Recall Reason
4/19/2023	**Ivenix Infusion System (Iis)** Large Volume Pump, Model No. LVP-0004	**FRESENIUS KABI USA, LLC** North Andover, Massachusetts	Fluid ingress that can cause a loss of electrical funtion and failure of the Set ID Sensory, resulting in the prevention of infusion or halt of infusion.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Ivenix Infusion System (Iis** UDI-DI: 00811505030320; Serial No.: 2118200008 - 2219200511	1546 Units Nationwide including California	March 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE