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 Ivenix Infusion System For Valve Mechanical Interference

Recall Date	Product Description	Recalling Firm	Recall Reason
12/27/2023	**Ivenix Infusion System (Iis)** Large Volume Pump LVP-0004	**FRESENIUS KABI USA, LLC** North Andover, Massachusetts	The device may experience mechanical interference on the Fluid Valve pins, which will trigger a Pump Problem alarm. The issue may lead to delay or interruption of therapy. Depending on the therapy and duration of delay/interruption, the issue may lead to serious harm or death.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Ivenix Infusion System (Iis)** UDI-DI 00811505030320 Serial numbers 2213800363 - 2213800231	938 Units Nationwide including California	December 2023 and prior.

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov