State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Baxter Healthcare Corporation for an Increase in Reported False Upstream Occlusion Alarms

Recall Date	Product Description	Recalling Firm	Recall Reason
7/19/2023	**SIGMA Spectrum Infusion Pump** Product Code 35700BAX2	**Baxter Healthcare Corporation** Deerfield, IL	A medical device correction is being issued for SIGMA Spectrum Infusion System (V8 Platform) and Spectrum IQ Infusion System with Dose IQ Safety Software infusion pumps due to an increase in reported false upstream occlusion alarms following upgrades to software versions v8.01.01 and v9.02.01.
7/19/2023	**The Spectrum IQ Infusion System with Dose IQ Safety Software** Product Code 3570009	**Baxter Healthcare Corporation** Deerfield, Illinois	An increase in reported false upstream occlusion alarms following upgrades to software versions v8.01.01 and v9.02.01

Recall Class	Product Identification	Distribution	Affected Dates
I	**SIGMA Spectrum Infusion Pump** GTIN 00085412498683, Software version v8.01.01, Serial Numbers	3306 Units Nationwide	April 2023 and Prior

I	**The Spectrum IQ Infusion System with Dose IQ Safety Software** UDI/DI 00085412610900, Software Version v9.02.01, All Serial Numbers	19861 Units Nationwide	April 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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