

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 recalls Spectrum Infusion Pumps for Non or Lowered Rate Delivery Under Usage Deviating from Instructions

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|-------------|--|---|--|
| 12/29/2021 | Baxter Spectrum IQ Infusion Pumps Product code 3570009 | Baxter Healthcare Corporation Deerfield, Illinois | Deviations from the Instructions for Use may lead to non-delivery or delivery of medication at a rate less than the programmed rate. |
| 12/29/2021 | Baxter SIGMA Spectrum Infusion Pump with Master Drug Library (Version 8), Product code 35700BAX2 | Baxter Healthcare Corporation Deerfield, Illinois | Non-delivery or lesser rate delivery of medication. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|-----------------|--|------------------------------|----------------------------|
| I | Baxter Spectrum IQ Infusion Pumps All serial numbers, GTIN 00085412610900. | 6,354 Units in California | December 2021 and prior |
| I | Baxter SIGMA Spectrum Infusion Pump All serial numbers, GTIN 00085412498683 | 6,746 Units in California | December 2021 and prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

