State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Smiths Medical Recalls Medfusion Syringe Pump for Potential of Therapy Interruption or Over-infusion

Recall Date	Product Description	Recalling Firm	Recall Reason
4/18/2022	**Medfusion Syringe Pump** Model 4000-0100-50, Model 4000-0101-249, Model 4000-0101-50, Model 4000-0101-51, Model 4000-0101-78, Model 4000-0105-249, Model 4000-0105-51, Model 4000-0105-78, Model 4000-0106-00, Model 4000-0106-01, Model 4000-0106-231	**Smiths Medical ASD Inc.** Minneapolis, Minnesota	Multiple issues with the potential for interruption of therapy or over-infusion: 1. Primary Audible Alarm (PAA), 2. Unanticipated Depleted Battery Alarms, 3. Time Base Alarm, 4. Intermittent Volume Over Time (IVOT) – Infusion Continues after System Failure, 5. Clearing of Program Volume Delivered (PVD), 6. False Alarm for Rate Below Recommended Minimum for Syringe Size, 7. Incorrect Bolus or Loading Dose Time Display, 8. Domain Name Server (DNS) Port 1001
4/18/2022	**Medfusion Syringe Pump** Models: 3500, 3500-0600-00, 3500-0600-01, 3500-0600-249, 3500-0600-50, 3500-0600-51, 3500-0600-82, 3500-306, 3500-402, 3500-414, 3500-415, 3500-500, 3500BC, 3500E, 3500G, 3500SD, 3500SD-500, 3500VX, 3500VX-306, 3500VX-414, 3500VX-415, 3500VX-500, 3500ZE, Software Versions 6.0.0, 6.0.1	**Smiths Medical ASD Inc.** Minneapolis, Minnesota	Multiple issues with the potential for interruption of therapy or over-infusion

Recall Class	Product Identification	Distribution	Affected Dates
I	**Medfusion Syringe Pump** Model 4000-0100-50: UDI 061058603532, Serial Numbers: 2000380 - 2016626	58671 Units Worldwide	April 2022 and prior
I	**Medfusion Syringe Pump** Model 3500: No UDI, Serial Numbers: Model 3500: No UDI, Serial Numbers: M63658 –M37660	65093 Units Worldwide	April 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE