State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Eitan Medical Ltd Recalls Sapphire Infusion Pumps For Failure To Detect Air In The Line

Recall Date	Product Description	Recalling Firm	Recall Reason
12/1/2023	**Sapphire Multi-Therapy Infusion Pump** REF 15031-000-0028	**EITAN MEDICAL LTD** Netanya, Israel	Software issues in software version Rev 16.10. Pumps may fail to detect air in the line when runn-ing on battery power.
12/1/2023	**Sapphire Epidural Infusion Pump** REF 15032-000-0027	**EITAN MEDICAL LTD** Netanya, Israel	Failure to detect air in the line.
12/1/2023	**Sapphire Plus Infusion Pump** REF 15038-000-0001	**EITAN MEDICAL LTD** Netanya, Israel	Failure to detect air in the line.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Sapphire Multi-Therapy Infusion Pump** UDI-DI: 15031-000-0028/7290109150109	1383 Total Units Nationwide	September 2023 and prior
I	**Sapphire Epidural Infusion Pump** UDI-DI: 15032-000-0027/7290109150147	1383 Total Units Nationwide	September 2023 and prior
I	**Sapphire Plus Infusion Pump** UDI-DI: 15038-000-0001/7290109150161	1383 Total Units Nationwide	September 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE or email Eitan Medical Ltd

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