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 Recalls Sapphire Infusion Pumps For Failing To Detect Air In Line

Recall Date	Product Description	Recalling Firm	Recall Reason
10/25/2023	**Sapphire Infusion Pumps** Models: Multi-Therapy (REF 15031-000-0028), Epidural (REF 15032-000-0027) and SapphirePlus (REF 15038-000-0001)	**EITAN MEDICAL LTD** Netanya, Israel	Infusion Pumps with affected software revision may fail to detect air in line, which may lead to air embolism.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Sapphire Infusion Pumps** Software Revision: 16.10.1 or 16.10.2 REF/UDI-DI: 15031-000-0028/7290109150109, 15032-000-0027/7290109150147, 15038-000-0001/7290109150161	1383 Units Nationwide including California	11 September 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE