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 Recalls Volara System For Risk Of Respiratory Distress In Ventilated Patients During Home Use

Recall Date	Product Description	Recalling Firm	Recall Reason
4/26/2022	**In-Line ventilator adaptor** M08473 OPTIMUS OLE	**Baxter Healthcare Corporation** Deerfield, Illinois	There is a potential of reduced oxygen-nation or pneumo-thorax/barotrauma to occur when the Vol-ara system is used with in-line ventilator in home care environment.
4/26/2022	**In-Line ventilator adaptor** M07937 MODULE, OPTIMUS HANDSET 2	**Baxter Healthcare Corporation** Deerfield, Illinois	There is a potential of reduced oxygen-nation

Recall Class	Product Identification	Distribution	Affected Dates
I	**In-Line ventilator adaptor** M08473 OPTIMUS OLE AC PAT.CIRCUIT KIT; UDI-DI: 00887761981492.	259 Units Nationwide including California	February 2020 to April 2022
I	**In-Line ventilator adaptor** M07937 MODULE, OPTIMUS HANDSET 2; UDI-DI: 00887761984622.	9 Units Nationwide including California	October 2019 to April 2022

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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