State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Covidien Recalls Puritan Bennett 980 Series Ventilator for Alarm Error

Recall Date	Product Description	Recalling Firm	Recall Reason
03/25/2021	**Puritan Bennett 980 Series Ventilator**	**Covidien, LP** North Haven, Connecticut	The audible alarm may not sound and/or the omni-directional LED visual alarm may not display during alarm states. Delayed awareness of alarm states may lead to delayed response or a delay of treatment, potentially resulting in hypoxia, dyspnea, cardiac arrest, or death.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Lot/Serial Number Product GTIN/MATNR 35B1300001 10884521172722 to 35B1401164 10884521172869**	16,563 Units Nationwide	March 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov