Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Radiometer Medical Aps Recalls Abl800 Flex

Recall Date	Product Description	Recalling Firm	Recall Reason
7/31/2024	**Abl800 Flex** The ABL800 FLEX analyzers are intended for: In Vitro testing of samples of whole blood for the parameters pH, pO2, pCO2, cK+, cNa+, cCa2+, cCl , cGlu, cLac, cCrea, ctBil, and co-oximetry parameters (ctHb, sO2, and the hemoglobin fractions FO2Hb, FCOHb, FMetHb, FHHb and FHbF); In vitro testing of samples of expired air for the parameters pO2 and pCO2; In vitro testing of pleura samples for the pH parameter.	**RADIOMETER MEDICAL APS** Bronshoj, Dk	Issue with analyzer when the pH of the calibration solution decreases during the in-use period potentially because of bacterial growth in the calibration solution bottles. This may result in a probability of reporting biased out-of-specification pH results on blood samples.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Abl800 Flex** UDI-DI/Model Numbers: 05700693938004/393-800, 393-801	93 Units in California	July 2024 and prior

For additional information, please visit the FDA website.