



California Device Recall Information Sheet

Food and Drug Branch - Device Recalls

SunMed Holdings, LLC Recalls Broselow Pediatric Emergency Rainbow Tape

Recall Date	Product Description	Recalling Firm	Recall Reason
6/20/25	Broselow Pediatric Emergency Rainbow Tape (distribution by AirLife); REF 7700REA AirLife brand, 2025 Edition, and 36-23446 Rev 2 Print Version The Broselow Tape is a length- and weight-based reference tool specifically designed for pediatric emergency care.	SunMed Holdings, LLC	The impacted tape was manufactured with incorrect information on the tape. Incorrect values are printed in the Red zone, Orange zone, and Grey zone. Using the incorrect values in the Red zone could lead to shocking a patient with an excessive dose of joules, causing significant harm including burns, heart damage, and cardiac arrest. Incorrect values in the Orange zone could lead to overdosing the patient with sodium bicarbonate and cause metabolic alkalosis, electrolyte imbalances, tissue

damage, and
worsen respiratory
status. Incorrect
information in the
Grey may lead to
underdosing the
patient with
sodium
bicarbonate and
may cause
reduced
myocardial
contractility,
decreased
response to
vasopressors, and
increased risk of
dysrhythmia.
uysmymma.

Recall Class	Product Identification	Distribution	Affected Dates
I	UDI-DI EA: 10889483588970 CS: 30889483588974 Lot 0004316661	9900 eaches US and Canada	May 2025 and prior.

For additional information, please visit <u>FDA Website</u>.