California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Edan Diagnostics – Fetal Monitor (F2, F3) Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
01/22/2026	EDAN Fetal Monitor (Models F2, F3), bedside fetal and maternal monitors used to track physiological parameters of pregnant women and fetuses from 28 weeks gestation, during antepartum and labor/delivery.	Edan Diagnostics San Diego, CA, USA	Potential cybersecurity vulnerabilities related to improper IP address configuration identified following an FDA It Has Come to Our Attention (IHCTOA) letter.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Lot Code:** N/A **Model No.:** F2, F3 **UDI-DI:** **F2:** 06944413800861 **F3:** 06944413800847 **S/N range:** Multiple serial numbers (see full list in recall data)	3,721 Units; Nationwide including California (**F2**: 1,256 units in CA; **F3**: 11 units in CA)	October 2025 and prior.

For additional information, please visit the FDA Website.