California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Angel Medical Systems, Inc. The Guardian

Recall Date	Product Description	Recalling Firm	Recall Reason
02/11/2025	Brand Name: The Guardian System Product Name: The Guardian Model/Catalog Number: Model AMSG3-E Product Description: The Guardian is the first FDA approved cardiac diagnostic implant that detects the onset of an ACS event and warns the patient to seek urgent medical care. The Guardian is an adjunct to patient recognized symptoms.	Angel Medical Systems, Inc.	Device reaching End of Service prematurely.

Recall Class	Product Identification	Distribution	Affected Dates
II	Model: AMSG3-E UDI-DI: 00850012625001 Battery Lots A1946, A1947, A1948, A1949, A1950, A2003, A2004, A2031, A2032, A2033, A2034, A2035, A2036, A2038, A2039, A2040, A2041, A2042, A2043	13 units in California with 3 affected by the recall reason.	September and prior

For additional information, please visit the FDA Website.