



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Avanos Medical Recalls Coolief Rf Generator For Producing F100 And F101 Faults

Recall Date	Product Description	Recalling Firm	Recall Reason
9/27/2023	Coolief Rf Generator An 80-watt Radio-Frequency (RF) Generator with four independent RF channels, allowing all RF channels to be activated individually or altogether. The system is controlled via a touch screen interface display that includes user controls, alarm messages, and on-screen selection of lesioning modalities.	AVANOS MEDICAL, INC. Alpharetta, Georgia	Avanos has received an increase in complaints from customers for COOLIEF RF Generators producing F100 and F101 faults.

Recall Class	Product Identification	Distribution	Affected Dates
II	Coolief Rf Generator STZ22277-006, STZ22277-007, STZ22277-008, STZ22277-009, STZ22277-010, STZ22277-011, STZ22277-012, STZ22277-013, STZ22277-014	24 Units Nationwide including California	1 August 2023 and prior

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