



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Medtronic Recalls HeartWare HVAD System Batteries Due to Battery Failure

Recall Date	Product Description	Recalling Firm	Recall Reason
5/05/2022	HeartWare Battery Model #1650DE, a component of the HeartWare Ventricular Assist Device (HVAD) System.	Medtronic Inc Minneapolis, Minnesota	Batteries for the HVAD system have a weld defect affecting internal components within the HVAD battery, resulting in the battery to malfunction and no longer provide power or prevent the battery from holding a complete charge or properly recharging.

Recall Class	Product Identification	Distribution	Affected Dates
I	GTIN 00888707008778. Serial numbers BAT935012 - BAT934966	429 Batteries Nationwide including California	April 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

