

State of California—Health and Human Services Agency

California Department of Public Health



Food and Drug Branch - Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Heartware Recalls Ventricular Assist Device Battery for Performance Issues

Recall Date	Product Description	Recalling Firm	Recall Reason
6/28/2022	HeartWare Ventricular Assist Device (HVAD) System Batteries Product Number 1650DE	Heartware, Inc. Miami Lakes, Florida	Battery performance issues. Battery electrical faults render it unable to power the controller, unable to accept charge from the battery charger, and/or result in the battery to appear to remain charged while discharging.

Recall Class	Product Identification	Distribution	Affected Dates
I	GTIN 00763000187767, Serial Numbers: BAT941874 - BAT943732	US Nationwide	June 2022 and prior.

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

