



California Medical Device Recall Information



Recall Name

HeartWare Recalls Certain Older HeartWare® Clinical Trial Controllers Due to ESD Susceptibility

Recall Date	Product Description	Recalling Firm	Recall Reason
02/20/15	HeartWare® Ventricular Assist System Controllers Product Codes: 1400 1401XX	HeartWare International, Inc. Miami Lakes, FL	<i>Affected controllers were distributed prior to 2012 for use in clinical trials.</i> <i>These controllers exhibit a higher susceptibility to electrostatic discharge (ESD) than newer commercial controllers.</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	Serial Numbers: CON000001 through CON005472	CA , nationwide	Distribution prior to 2012

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm435802.htm>