



# California Medical Device Recall Information



## Recall Name

**Thoratec Corporation Recalls HeartMate II® LVAS Pocket System Controller  
To Update Labeling and Training Materials**

Recall Date	Product Description	Recalling Firm	Recall Reason
03/04/14	HeartMate II® LVAS Pocket System Controller	<b>Thoratec Corporation</b> Pleasanton, CA	<i>There have been four reports of death and five reports of loss of consciousness or other symptoms of hypoperfusion when changing from a primary system controller to backup system controller.</i>  <i>All patients using the Pocket Controller should be re-trained and provided the updated Patient Handbook information.</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	<b>All controllers</b> (up to the date of recall)	<b>CA</b> , nationwide	Distribution began: <ul style="list-style-type: none"> <li>• August 2012 – EU;</li> <li>• May 2013 – US, Canada</li> </ul>

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm387994.htm>