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Class 1 Device Recall HVAD

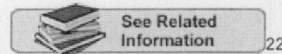


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Class 1 Device Recall HVAD



Date Initiated by Firm	June 08, 2016
Create Date	October 17, 2016
Recall Status¹	Open ³ , Classified
Recall Number	Z-0005-2017
Recall Event ID	<u>72001</u> ²³
PMA Number	<u>P100047</u> ²⁴
Product Classification	<u>Ventricular (assist) bypass</u> ²⁵ - Product Code <u>DSQ</u> ²⁶
Product	HeartWare Ventricular Assist System Controller
	<p>Product Usage: For use as a bridge-to-cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HVAD is designed for in-hospital and out-of-hospital settings, including transportation via fix-wing aircraft or helicopter</p>
Code Information	All Heartware Controllers manufactured after September 2014., US Model No: 1400, 1401XX, 1403US. , International Model No: 1400, 1401XX, 1407XX.
Recalling Firm/ Manufacturer	HeartWare Inc 14400 NW 60th Ave Miami Lakes FL 33014-2807
For Additional Information Contact	Customer Service 305-364-1575
Manufacturer Reason for Recall	Loose connector ports in controller body.
FDA Determined Cause²	Under Investigation by firm
Action	HeartWare sent an Urgent Medical Device Correction letter dated June 8, 2016, to all affected customers, HeartWare advised clinicians to remind patients to follow unit instructions and water avoidance, and to regularly schedule appointments to check the integrity of the unit and to be cautious with connectors when inspecting connectors. Clinicians were also instructed to send back the enclosed "Acknowledgement Form" within 30 days and to forward the message to necessary individuals within their organization. Customers with questions were instructed to contact their local HeartWare representative. For questions regarding this recall call 305-364-1575.
Quantity in Commerce	8799 Worldwide, 4,564 in US
Distribution	Worldwide Distribution - US Nationwide in the states of AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, IL, IN, KY, LA, MA, MD, MI, MN, MO, MS, NC, NE, NJ, NY, OH, OK, OR, PA, SC, TN, TX, UT, VA, WA, and WI and countries of Australia, Austria, Belgium, Canada, France, Germany, Lebanon, Malaysia, Sweden, Switzerland, & United Kingdom.