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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 Status: Open, Classified
Recall Number: Z-0005-2017
Recall Event ID: 72001
PMA Number: P100047
Product Classification: Ventricular (assist) bypass - Product Code DSO
Product: HeartWare Ventricular Assist System Controller

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 fixed-wing aircraft or helicopter.

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 Cause: 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.

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