Medtronic News

FDA Classifies Two Field Actions Related to HeartWare HVAD System as Class 1 Recalls

DUBLIN - Sept. 30, 2016 - Medtronic plc (NYSE:MDT) announced today that two previously communicated global voluntary recalls related to the HeartWare International (HeartWare) HVAD® System have been classified as Class 1 by the U.S. Food and Drug Administration (FDA). Class 1 recalls describe situations where there is reasonable risk of serious adverse health consequences or death.

In a safety notification letter distributed globally in May and June 2016, HeartWare® notified physicians regarding potential damage to controllers from exposure to moisture through loose power and data connectors. In the U.S., all clinician notifications have been acknowledged, and globally 99 percent of clinician notifications have been acknowledged.

Hospital clinicians were advised to inspect patients' HVAD HeartWare Controllers for loose connectors at patients' regularly scheduled appointments and to replace affected controllers with a new controller at the clinicians' discretion. Clinicians also were advised to remind patients about the safe use of the HVAD System, particularly with regard to moisture and proper connection to power and data sources. Damage to the controllers from this issue could cause loss of communication between the controller and monitor, reduced ability to detect alarms or interruption of circulatory support due to pump stop, which could lead to serious injury or death.

HeartWare controllers subject to this safety notification include the following models sold worldwide:

Model No.
1400
1401

At the initiation of this recall, approximately 8,799 potentially affected HVAD HeartWare Controllers with these model numbers had been distributed and remained in use by patients, worldwide. As of Sept. 26, 2016, this recall and subsequent inspection of patients' controllers has resulted in the replacement of 308 affected HVAD controllers worldwide.

In August 2016, HeartWare issued a global voluntary recall of certain models of unimplanted, sterile HVAD® Pump Implant Kits (pumps) in hospital inventory. The HVAD pumps contained in these sterile implant kits may be susceptible to electrical faults and connection failures if fluid enters the driveline-to-controller connector during or after the implant procedure. Electrical faults or connection failures could interrupt circulatory support due to a pump stop, potentially resulting in serious injury or death. In the U.S., all clinician notifications have been acknowledged, and globally 89 percent of clinician notifications have been acknowledged.

Clinicians were advised to review hospital inventories for HVAD implant kits (pumps) with serial numbers lower than HW25838 with the following model number and notify the company for replacement:

Model No.
1103
1104

At the initiation of this recall, 350 potentially affected HeartWare HVAD implant kits with these model numbers had been distributed and remained in hospital inventories, worldwide. As of Sept. 26, 2016, 323 of the 350 implant kits, or 92 percent, have been used or returned to HeartWare.

Medtronic acquired HeartWare on Aug. 23, 2016; the combined organization is committed to putting patient safety and customers first and to implementing manufacturing enhancements to address these issues.

The HVAD System includes a ventricular assist device (VAD), or mechanical pump, that pumps blood to the body when one of the heart's natural pumps (a ventricle) does not perform well. The controller is a small computer that monitors the pump. These implanted systems can allow people with advanced heart failure to return to a fuller life while they await heart transplantation.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Clinicians with questions should contact their HeartWare representative, call Medtronic HeartWare's 24-hour Clinical Support line at (888) 494-6365 or email FSCA@heartware.com.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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