Medtronic News

FDA Designates Medtronic Worldwide Voluntary Field Action on HVAD(TM) System Controllers and DC Adapters as Class I Recall

DUBLIN - April 18, 2017 - Medtronic plc (NYSE: MDT) announced today that the U.S. Food and Drug Administration (FDA) has classified the company's recently initiated voluntary field action related to its HVAD(TM) System Controllers (serial numbers lower than CON300000) and DC Adapters (all serial numbers for product code 1435) as a Class I recall.

Medtronic began notifying clinicians outside of the United States in March 2017 about updated HVAD System Controllers and DC Adapters that were developed following two previously communicated Field Safety Notices that occurred in April 2015 and April 2016. The FDA approved the updated controller on April 7, 2017, and Medtronic began notifying U.S. clinicians about the updated HVAD Controllers and DC Adapters on April 14, 2017.

The updated controller includes enhancements designed to address the potential safety issues identified in the previously communicated notices, including:

- strengthened power and serial port alignment guides intended to reduce the incidence of wear that could lead to damaged connector pins;
- functionality designed to monitor internal battery performance and sound an alert when the internal battery is nearing depletion; and
- redesigned connectors and housing intended to prevent the risk of connectors loosening or becoming more vulnerable to damage from exposure to water and other fluids.

In addition, the updated controller introduces upgraded internal circuitry designed to improve overall device reliability.

In April 2015 and April 2016, Medtronic notified clinicians about potential safety issues with the current HVAD System Controller that could lead to possible injury and death due to worn alignment guides, internal "double disconnect (no power) alarm" battery failure, and loose power and data connectors.

With the introduction of the updated controller, Medtronic has begun to remove current HVAD Controllers (product codes 1400,1401US and 1407US) in select geographies, including the U.S. Medtronic also has begun to remove the related adapters (product code 1435), Instructions for Use, Patient Manuals and Emergency Responder Guides.

As part of these activities, Medtronic has provided the following recommendations to physicians:

- Before the updated controller will be distributed to hospitals, clinicians must complete required training on the updated controller and updated product labeling, including the Instructions for Use and Patient Manual.
- Following training and the receipt of the updated controllers in hospital inventory, clinicians are requested to quarantine and replace patients' primary and backup HVAD Controllers and DC adapters under clinical supervision and at a hospital where patient support equipment is available.
- While Medtronic recommends that HVAD Controllers be exchanged, clinicians should weigh the benefits of the updated controller against the risks of a controller exchange procedure.
- When clinicians determine a controller exchange is appropriate, they will notify patients who should promptly schedule a controller exchange as soon as the updated controllers are available.
- Trained hospital staff must educate patients on using the updated controller.

Patients with questions about this announcement should contact their physicians or ventricular assist device (VAD) coordinator at their hospital center.

Adverse reactions or quality problems experienced with the use of this device 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

For information or to report a problem, please contact the 24-hour Clinical Support line at +1-888-494-6365 or email FSCA@medtronic.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 more than 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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