Medtronic News

Physio-Control Resumes Unrestricted Global Shipments of Its LIFEPAK(R) Defibrillators

REDMOND, Wash., Feb 19, 2010 (BUSINESS WIRE) -- Physio-Control Inc., a wholly-owned subsidiary of Medtronic, Inc. (NYSE: MDT), announced today it received notice from the U.S. Food and Drug Administration (FDA) that having successfully met requirements for improvements to the quality system, the company may resume unrestricted worldwide shipments of its external defibrillators.

In May 2008, Physio-Control signed a Consent Decree with the FDA to address issues the Agency raised during inspections of the company's quality system. Under the terms of this agreement, Physio-Control was permitted to ship a limited number of products to emergency care providers to meet public health and safety needs until quality system improvements were completed.

"We dedicated significant energy and resources to establishing a new operating standard for our quality system and we are pleased it has met with the FDA's approval," said Brian Webster, president of Physio-Control. "The investments we've made not only in our quality system, but also in our design and manufacturing processes, will ensure our products and services continue to meet both our customers' high expectations and those of the regulatory agencies. The quality of the products shipping from Physio-Control today is higher than it has ever been in our 55-year history. I believe the challenges we faced, and the way we met them, have made Physio-Control a stronger company for the long-term."

"Our quality system investments have also led to more streamlined innovation and product development capabilities," said Webster. During the past two years, Physio-Control has received FDA 510(k) clearance of the LIFEPAK 15 monitor/defibrillator, the LIFEPAK 20e defibrillator/monitor and the LIFENET(R) System Version 4.1, the latest update of its web-based platform for capturing and sharing emergent STEMI patient data. The company also introduced a new battery-operated version of the LUCAS(TM) Chest Compression System, a portable, easy-to-use device that delivers automated chest compressions to improve blood flow in victims of cardiac arrest.

"We accept responsibility for leading our industry not only in clinical innovation, but also in quality system performance and regulatory compliance," added Webster. "We are committed to raising the bar on product quality and reliability. While this has been a difficult period in our recent history, we are very proud to reach this milestone with the FDA and have the opportunity to thank our customers who have remained loyal to Physio-Control products. The end results of this journey will be strengthened engagement with our customers, and best-in-class products that will support the emergency care community."

About Physio-Control

Physio-Control, a wholly-owned subsidiary of Medtronic, Inc., is located in Redmond, Wash. Physio-Control pioneered defibrillation technology 55 years ago. The company is the world's leading provider of external defibrillation and monitoring technology for the treatment of sudden cardiac arrest and other cardiorespiratory emergencies. To find out more about Physio-Control, go to www.physio-control.com or call 1-800-442-1142.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

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.

SOURCE: Medtronic, Inc.

Medtronic, Inc.
Jeff Warren, 763-505-2696
Investor Relations
or
Jennifer Roth, 425-867-4393
Public Relations

---

https://news.medtronic.com/2010-02-19-Physio-Control-Resumes-Unrestricted-Global-Shipments-of-Its-LIFEPAK-R-Defibrillators