

Physio-Control

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News bulletin

Physio-Control Receives Premarket Approval From the FDA On Its Full Portfolio of LIFEPAK® Professional Devices

Redmond, Washington, USA – July 27, 2018 – Physio-Control, now part of Stryker, today announced it has received premarket approval (PMA) by the U.S. Food and Drug Administration (FDA) to continue to market and distribute its full line of LIFEPAK professional defibrillators in the U.S.

The list of professional-use defibrillators that received PMA approval include: LIFEPAK 1000 defibrillator, LIFEPAK 20 (Refurbished) defibrillator/monitor, LIFEPAK 20e defibrillator/monitor and LIFEPAK 15 monitor/defibrillator.

“Physio-Control is excited to have reached this major milestone with our complete portfolio of devices in both the professional and public safety markets,” says Anne Mullally, Vice President and GM, Stryker EMS and Physio-Control. “This is the culmination of several years of significant work, substantiating the safety and effectiveness of our devices, and is the highest bar FDA Class III medical devices must meet. This represents our continued commitment to producing the most reliable, highest quality, and science-driven products that our customers need to support their patients and communities.”

In January 12, 2017 following an extensive submission, Physio-Control’s HeartSine® business group based in Belfast, Ireland, was the first AED manufacturer to receive PMA for the three HeartSine samaritan® models SAM 350P, SAM 360P and SAM 450P automated external defibrillators (AEDs) as well as the Pad-Pak™, Pediatric-Pak™, TSO-certified Pad-Pak and Saver EVO™ software. Physio-Control’s AEDs, LIFEPAK CR® Plus and LIFEPAK EXPRESS, received PMA on December 21, 2017.

About Physio-Control, now part of Stryker

Physio-Control, now part of Stryker, is the world’s leading provider of professional emergency medical response solutions that predict or intervene in life-threatening emergencies. The company’s products include LIFEPAK® monitor/defibrillators and automated external defibrillators, LUCAS® Chest Compression Systems, the LIFENET® System, HeartSine® AEDs and more. Learn more at physio-control.com, or connect on [Facebook](#), [LinkedIn](#) or [Twitter](#)

About Stryker

Stryker is one of the world’s leading medical technology companies and, together with its customers, is driven to make healthcare better. The company offers innovative products and services in Orthopaedics, Medical and Surgical, and Neurotechnology and Spine that help improve patient and hospital outcomes. More information is available at www.stryker.com.

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