LivaNova Receives 510(k) Clearance for ECMO from FDA for LifeSPARC, the Next-generation Advanced Circulatory Support System

November 17, 2022 2:00 PM EST

Platform simplifies life support, making life-saving technology more accessible to hospitals and critically ill patients

LONDON--(BUSINESS WIRE)--Nov. 17, 2022-- LivaNova PLC (Nasdaq: LIVN), a market-leading medical technology and innovation company, today announced it received 510(k) clearance for extracorporeal membrane oxygenation (ECMO) from the U.S. Food and Drug Administration (FDA) for LifeSPARC™, the Company's next-generation Advanced Circulatory Support (ACS) pump and controller system.LivaNova leveraged existing real-world evidence inclusive of data collected during the COVID-19 pandemic to receive this new indication.

"The onset of the global pandemic elevated ECMO to the forefront as an effective treatment option for patients in need of emergent rescue who had limited, if any, options," said Dr. Raymond Yau, Director of Cardiogenic Shock at Heart Hospital of New Mexico in Albuquerque. "The past couple of years have demonstrated the inherent value of the LifeSPARC system, which offers even the sickest patients a chance at survival. With LifeSPARC, simplified and streamlined ECMO is in reach for healthcare centers of all sizes."

The LifeSPARC pump and controller system simplifies ECMO to ensure that hospitals of all sizes can access this high level of life support. The LifeSPARC controller was designed to remove complexity often seen with ECMO devices, instead offering a streamlined user interface and simple navigation panel. This simplicity increases accessibility and ease of use for hospital staff. The LifeSPARC pump is centrifugal and designed to reduce priming time to minutes. The on-patient pump design allows for a miniaturized circuit, making it easy to transport within the hospital and optimizing circuit management for intensive care unit staff. This led to swift device adoption by customers, providing ECMO to critically ill patients during the COVID-19 pandemic.

LifeSPARC received an initial 510(k) FDA clearance in July 2019 for up to six hours of use for cardiopulmonary bypass. In April 2020 and with the onset of the COVID-19 pandemic, the FDA issued temporary emergency guidelines for ECMO therapy beyond six hours. Several products within the LivaNova ACS portfolio, including LifeSPARC, were included in the temporary guidance and thereby made available to support COVID-19 patients across the U.S. This latest 510(k) clearance allows for the LifeSPARC system to be used for ECMO beyond six hours with patients in acute respiratory failure or acute cardiopulmonary failure, including but not limited to those receiving treatment for COVID-19.

"There is a growing need for simplified life support and with the LifeSPARC pump and controller, we have the opportunity to make ECMO an option for more patients in more places," said Ryan Miller, President of the ACS business unit at LivaNova. "Since FDA published an enforcement policy to temporarily expand indications in 2020, many hospitals began using LifeSPARC and experienced its benefits firsthand. With the relative simplicity and portability of the system, more patients can have access to life-saving ECMO regardless of the hospital size where they are treated."

The LifeSPARC System was built on more than 20 years of life support experience with TandemHeart™, the first-generation ACS system. LifeSPARC simplified the priming process and increased the power of the pump, while leveraging the strengths of the previous generation system. The console and pump are complemented by four ready-to-deploy kits that offer a variety of cannulation configurations to support cardiac and cardiopulmonary conditions. LifeSPARC assists in circulating a patient's blood when part of an extracorporeal circuit, including physiologic gas exchange. It is intended for use in adult patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

Notably, as of November 8, LivaNova achieved a 100% customer response rate for the LifeSPARC Critical Failure (CF) field action, which was required by FDA under a recent recall and related to modifications made to the Operations Manual for the LifeSPARC controller to address situations during which certain users were unintentionally stopping the pump in response to a screen error message. As part of the 510(k) clearance, LifeSPARC controller software updates have been reviewed and cleared by FDA, thus allowing LivaNova to contact customers to implement the updates. For more information, please visit the dedicated page on the LivaNova website.

About LivaNova

LivaNova PLC is a global medical technology and innovation company built on nearly five decades of experience and a relentless commitment to provide hope for patients and their families through innovative medical technologies, delivering life-changing improvements for both the Head and Heart. Headquartered in London, LivaNova employs approximately 3,000 employees and has a presence in more than 100 countries for the benefit of patients, healthcare professionals and healthcare systems worldwide. For more information, please visit www.livanova.com.

Safe Harbor Statement

This news release contains "forward-looking statements" concerning the Company's goals, beliefs, expectations, strategies, objectives, plans and underlying assumptions and other statements that are not necessarily based on historical facts. These statements include, but are not limited to, statements regarding LifeSPARC and the ACS product portfolio. Actual events may differ materially from those indicated in our forward-looking statements as a result of various factors, including those factors set forth in Item 1A of the Company's most recent Annual Report on Form 10-K, as supplemented by any risk factors contained in Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. LivaNova undertakes no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

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Source: LivaNova PLC