Nuwellis Receives FDA Clearance for an Additional Dual Lumen Extended Length Peripheral Catheter

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Specialty catheter provides alternative peripheral access for ultrafiltration therapy across a greater range of patient physiologies

MINNEAPOLIS, Jan. 04, 2024 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company focused on transforming the lives of people with fluid overload, today announced it has received U.S. Food and Drug Administration (FDA) clearance for its specialty peripheral dual lumen extended length catheter (dELC). The addition of a new 12 cm catheter provides clinicians who treat patients with fluid overload with an additional venous access option to use the company's Aquadex ® ultrafiltration system.

"Expanding peripheral venous access options through our dELC comes at an important time, as healthcare providers work to bring ultrafiltration therapy to patients within ICU and stepdown units," said Nestor Jaramillo, Jr., President and Chief Executive Officer of Nuwellis. "Our unwavering commitment is to make Aquadex safe, effective, and easy to administer to the countless patients suffering from fluid overload, because of heart failure or critical illnesses, in our healthcare systems."

Nuwellis' dELC specialty catheter is available in two lengths and provides alternative peripheral access for ultrafiltration therapy across a broad range of patient physiologies. The new 12 cm dELC has the same features as the longer 16 cm option offered by the company but eliminates the need for trimming when a shorter catheter is needed. The dELC offers the performance capabilities of a central catheter from the periphery, and its unique inner coil design ensures consistent blood flow and prevents kinking.

"The tenacity and dedication of our research and development team is driving advancements in our products and bringing Aquadex to more patients who can benefit from the therapy," said Vitaliy Epshteyn, Nuwellis' Senior Vice President of Operations, Engineering, Quality, and Regulatory. "We extend our gratitude to the FDA for its swift review and clearance of the dELC catheter, marking a significant milestone on our mission to transform fluid management."

Aquadex is proven to simply, safely, and precisely remove excess fluid from patients suffering from fluid overload who have not responded to conventional medical management, including diuretics. Providers can specify and adjust the rate of fluid removed for each individual patient, resulting in a gradual reduction of excess fluid. The device's built-in, customizable hematocrit monitoring technology provides real-time measurement of percent blood volume changes that can be tailored to individual patients' needs. A customizable fluid removal rate is particularly important for pediatric patients, who have a small amount of blood in their bodies. The Aquadex system is cleared by the FDA for use in adults and pediatric patients weighing 20 kg (44 lbs.) or more.

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical technology company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The company is focused on commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly owned subsidiary in Ireland. For more information visit www.nuwellis.com or visit us on LinkedIn or Twitter.

About the Aquadex SmartFlow® System

The Aquadex SmartFlow system delivers clinically proven therapy using a simple, flexible and smart method of removing excess fluid from patients suffering from hypervolemia (fluid overload). The Aquadex SmartFlow system is indicated for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kg or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a health care provider, within an outpatient or inpatient clinical setting, under physician prescription, both having received training in extracorporeal therapies.

Forward-Looking Statements

Certain statements in this release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation, statements regarding the new market opportunities and anticipated growth in 2024 and beyond. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this release, including, without limitation, those risks associated with our ability to execute on our commercialization strategy, the impact of the COVID-19 pandemic, the possibility that we may be unable to raise sufficient funds necessary for our anticipated operations, our post-market clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, intellectual property protection, our ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired businesses, and other risks and uncertainties described in our filings with the SEC. Forward-looking statements speak only as of the date when made. Nuwellis does not assume any obligation to publicly update or revise any forward-looking statements, whether due to new information, future events or otherwise.

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