Nuwellis Receives CE Mark for 24-Hour Blood Circuit Set

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Certification will help Nuwellis meet clinical and healthcare economic needs in Europe and make outpatient ultrafiltration treatment more accessible

EDEN PRAIRIE, Minn., Sept. 21, 2021 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (NASDAQ: NUWE), a company focused on providing solutions for patients suffering from fluid overload, today announced that it has received CE Mark Certification for its 24-Hour Blood Circuit Set (UF 500-24 Hour). The UF 500-24 Hour blood circuit set is only to be used with the company's Aquadex SmartFlow® system. The CE marking allows Nuwellis to market the 24-hour Blood Circuit in the European Union (EU) and all other countries that recognize this certification.

The new device will help Nuwellis expand access to ultrafiltration among patients who need no more than 24 hours of Aquadex therapy in the inpatient setting. Additionally, this circuit can provide a more economical solution for hospitals to treat patients in the outpatient/ambulatory setting, where therapy can be delivered for up to 8 hours. Such use in the outpatient setting provides Nuwellis the flexibility to better meet the clinical and healthcare economic needs of European markets, while at the same time improving lives by seeking to prevent hospitalizations.

“For the past two years, we have watched hospitals around the world experience tremendous capacity pressures, which has further emphasized the important role that the ambulatory setting can play in patient care,” said Nestor Jaramillo, Jr., president and CEO of Nuwellis. “Receiving CE certification for the 24-hour Aquadex circuit will make outpatient ultrafiltration treatment more accessible for patients not responding to oral diuretics who may be at risk of hospitalization.”

The Aquadex SmartFlow System simply, safely, and precisely removes excess fluid (primarily salt and water) from patients suffering from fluid overload who have not responded to 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. Up to 500 mL per hour of excess fluid can be removed.

The 24-hour blood circuit is part of the Aquadex SmartFlow system, which consists of three components:

- The console, which allows caregivers precise control of ultrafiltration therapy.
- The peripheral catheter, which draws blood from and returns blood to the patient.
- The blood circuit set, which filters the patient’s blood and collects excess water and salt.

Ambulatory care is one of the fastest-growing and highest-margin segments of the healthcare industry, according to a 2020 study by McKinsey & Company. In the United States, there has also been continuous development and expansion of healthcare treatments in the outpatient market. These trends have been accelerated by the COVID-19 pandemic and are expected to continue to grow as clinical technology improves, providers and payers incentivize out-of-hospital care, and consumers demand lower costs, improved access and better experiences.

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical device company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The Company is focused on developing, manufacturing and commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, Minn., with a wholly-owned subsidiary in Ireland.

About the Aquadex SmartFlow System

The Aquadex SmartFlow system delivers clinically proven therapy using a simple, flexible and predictable 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.

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