

chf solutions

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FOR IMMEDIATE RELEASE

CHF SOLUTIONS RECEIVES FDA 510(K) MARKETING CLEARANCE FOR CENTRAL VENOUS ACCESS WITH FLUID REMOVAL SYSTEM

BROOKLYN PARK, Minn., December 9, 2003 – CHF Solutions, a private medical device manufacturer, has received 510(k) marketing clearance from the U.S. Food and Drug Administration for the use of central venous access with its System 100 Fluid Removal System, a mechanical pump/ultrafiltration system that removes excess fluid from fluid-overloaded patients. The company received FDA marketing clearance for the System 100 and peripheral access (e.g. a vein in the arm) in mid-2002.

Central venous access involves inserting a small flexible catheter into the vascular system, often with the tip located in a large vein near the heart. Sites of catheter insertion may be an arm, jugular vein or vein near the clavicle (collar bone).

“Marketing clearance for central venous access provides physicians using the System 100 with an additional access option,” said John L. Erb, CHF Solutions chief executive officer. “In many hospitalized patients with fluid overload, central venous access has already been established. With this marketing clearance, the same access point can be used to remove fluid reliably and predictably with the System 100. Central access can be appropriate for medical or surgical patients with fluid overload who require intensive care. With this central access indication, System 100 use can potentially expand. For

(more)

example, 7 to 10 percent of open-heart surgery patients suffer from extended fluid overload postoperatively.”

About the System 100

The System 100 is a technologically sophisticated – yet easy to use – mechanical pump/ultrafiltration system that can remove up to four liters (one gallon) of excess fluid from the body over eight hours. Conventional diuretic treatment typically takes several days. Physicians can specify and adjust the amount and rate of fluid to be removed, with no clinically significant impact on blood chemistry, blood pressure or heart rate. A standard catheter inserted into a peripheral or central vein connects the patient to CHF Solutions’ System 100.

In a System 100 treatment study involving congestive heart failure patients with fluid overload, overall health benefits were substantial enough to improve patients’ overall heart ranking on the New York Heart Association classification scale, a widely used measurement. Further, System 100 treatment reduced hospital stays by two days, when compared to patients receiving conventional diuretic treatment – a significant cost savings. Patients lost an average of five pounds (primarily water), reducing weight straining the heart and often increasing mobility. Many patients who had been sleeping in chairs to ease breathing could return to sleeping in a horizontal position. Some patients, whose feet were so swollen that they couldn’t wear shoes, left the hospital with their shoes laced up.

Fluid Overload and Congestive Heart Failure

Patients with congestive heart failure represent the largest group of fluid-overload patients. Fluid overload can be caused by many things, including renal failure, post-surgical fluid overload, metabolic disease and congestive heart failure.

Congestive heart failure (CHF) is the progressive inability of the heart to pump enough blood to support the vital organs; deterioration of the heart muscle leads to decreased pumping capacity, elevated stress on the heart and increased fluid retention. In the United States each year, there are 3.1 million hospital admissions for congestive heart failure, at a cost of more than \$23 billion.

An estimated 5 million people suffer from the condition in the United States. Congestive heart failure is the fastest-growing cardiovascular disease, with 550,000 diagnoses annually in the United States. The American Heart Association calls congestive heart failure “the disease of the millennium.”

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About CHF Solutions

CHF Solutions, based in Brooklyn Park, Minn., is a privately held manufacturer of innovative medical devices for cardiac care. The company's mission is to provide medical practitioners with innovative and proprietary solutions that enable the treatment of patients with unmet clinical needs. For additional information about the System 100 and CHF Solutions, visit www.chfsolutions.com.

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