

chf solutions

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FOR IMMEDIATE RELEASE

CHF SOLUTIONS RECEIVES FDA 510(K) MARKETING CLEARANCE FOR SYSTEM 100™ FLUID REMOVAL SYSTEM

Innovative Technology Has the Potential to Improve Quality of Life For Patients Suffering from Fluid Overload

BROOKLYN PARK, Minn., June 4, 2002 – CHF Solutions, Inc., a private medical device manufacturer, has received 510(k) marketing clearance from the U.S. Food and Drug Administration for its System 100™ Fluid Removal System, a mechanical pump ultrafiltration system that removes excess fluid from fluid-overloaded patients. The company plans a limited market launch at selected medical centers in early June, followed by a national rollout in the third quarter of 2002.

Fluid overload can be caused by many things including renal failure, post-surgical fluid overload, metabolic disease and congestive heart failure. Patients with congestive heart failure represent the largest group of fluid-overload patients. 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. With the aging population, congestive heart failure diagnoses are growing eight percent annually in this country. The American Heart Association (AHA) calls congestive heart failure "the disease of the millennium."

Fluid overload can cause severe fatigue, shortness of breath and subsequent hospitalizations. The market potential for treating fluid overload is very large. For congestive heart failure alone, an estimated five million people suffer from the condition in the United States, incurring 3.1 million hospital admissions at a cost of more than \$23 billion annually.

"Market clearance for our product is very good news for the increasing number of people with fluid overload," said John L. Erb, CHF Solutions chief executive officer. "At CHF Solutions, our mission is to provide cardiologists with innovative tools that can improve the quality of life for patients who suffer from fluid overload. The System 100™ is unique in its ability to remove fluid safely and at a controlled rate æ an alternative to drug therapies with significant risks and extended hospitalizations."

The System 100™ has the potential to reduce days in the hospital dramatically. In light of the fact that Medicare reimbursement only covers about half of the typical \$10,000 cost of hospitalization for fluid overload associated with congestive heart failure, there is significant interest in the cost effectiveness of the System 100™. The cost of the therapy is under \$1,000 and will be reimbursed under current DRG codes.

(more)

How the Product Works

The System 100™ allows a cardiologist or nurse to extract a targeted volume of fluid from the blood at a precisely controlled rate using a technique called ultrafiltration that separates the excess fluid from the blood. The System 100™ utilizes a proprietary blood circuit/filter and an easy-to-use, reusable console to perform ultrafiltration. It connects to the blood stream through catheters inserted into peripheral veins, typically in the arms. The ability to predictably remove excess fluid reduces the risk of removing too much fluid too quickly, which can result in low blood pressure and vital organ damage.

The CHF Solutions technology offers a rapid, precise and safe approach to treating fluid overload. The System 100™ removes two to four liters of fluid in a four- to eight-hour period. In contrast, standard intravenous diuretic drugs are used cautiously due to their increased risk and may take two to three days in the hospital to achieve similar results. In addition, the System 100™ has been shown to have no impact on blood chemistry, blood pressure and heart rate.

CHF Solutions completed the Simple Access Fluid Extraction (SAFE) clinical trial and submitted the data to the FDA. The SAFE trial showed that the System 100™ Fluid Removal System can be used safely and effectively for temporary ultrafiltration of patients with fluid overload.

About CHF Solutions

CHF Solutions, Inc., based in Brooklyn Park, Minn., designs and manufactures mechanical pump/filter systems to remove excess fluid in fluid overloaded patients and improve their quality of life. The company's mission is to provide cardiologists with innovative tools to better manage fluid overload patients and to significantly reduce health care costs. For additional information, visit www.chfsolutions.com.

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