

Nephros Receives 510k Approval for Dual Stage Ultrafilters

RIVER EDGE, N.J., July 2 /PRNewswire-FirstCall/ -- Nephros, Inc. (OTC Bulletin Board: NEPH), a medical device company developing and marketing filtration products for therapeutic applications, infection control, and water purification, today reported that it has received 510k approval from the U.S. FDA to market its Dual Stage Ultrafilters (DSU) for in-line purification of dialysate water and bicarbonate solution.

On July 1, 2009, Nephros received approval of the DSU to be used to filter biological contaminants from water and bicarbonate concentrate used in hemodialysis procedures. "The DSU is Nephros's first FDA approved device in the U.S. and represents an important milestone for the company," said Ernest Elgin, President and CEO of Nephros, Inc., "within dialysis clinics, microbial and endotoxin contamination of the water and dialysate concentrate used to prepare dialysate is an ongoing concern. Nephros's DSU filters are designed to eliminate these contaminants."

Within the U.S., there are approximately 4,500 clinics providing over 50 million dialysis treatments to 350,000 patients annually. To perform dialysis, ultrapure water is crucial to the production of dialysate. Dialysis clinics have water purification systems; however, microbial contaminants can originate from the water treatment system, the water distribution loop, or the dialysate concentrates. The Nephros DSU filters particles down to the 0.005-micron level and addresses dialysate contaminants at crucial points: after the reverse osmosis module and at the dialysis machine entrance from the water distribution loop. The DSU filter can be used as the last step in the water purification process to ensure ultra pure water for dialysis procedures. Regular use of Nephros Dual Stage Ultra Filters offers an affordable safety measure when utilized with modern water treatment systems and optimally designed hemodialysis machines.