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EKOS Corporation Receives CE Mark to Treat Massive and Sub-Massive Pulmonary Embolism

Cutting-Edge Technology First in the World

BOTHELL, Wash.--([BUSINESS WIRE](#))--EKOS Corporation announced today the EKOS EkoSonic® Endovascular System is the first endovascular device approved for the treatment of pulmonary embolism (PE). The EkoSonic® System, which was originally designed and approved to dissolve blood clots in the arms and legs, now has the added indication for treating this major unmet medical need.

Robert W. Hubert, President/CEO said, "The CE mark is an important milestone for EKOS and a clear demonstration of our ongoing commitment to champion a better solution for treatment of PE. Hospitals in Europe may now begin ordering and using the EKOS device for this indication."

Pulmonary embolism occurs in approximately 1 million patients in Europe annually (600,000 in the US), causing or contributing to 300,000 deaths each year. A PE is caused when a large blood clot obstructs the major blood vessels leading from the heart to the lungs. The victim's heart is suddenly overwhelmed with the task of pushing blood past this obstruction. Symptoms are similar to a heart attack.

About 5% of PEs are massive; resulting in rapid heart failure and shock. Without immediate therapy death can occur. A large dose of clot-dissolving drug called a thrombolytic, delivered to a vein was the only approved therapy for these patients; however, unintended bleeding, often fatal itself, is a much feared side-effect. Up to 40% of PE victims have less critical obstructions, often called sub-massive PE, which are currently treated with anti-coagulant medication. These medications do not remove clot; they simply prevent the clot from growing larger. Recent, studies suggest that failure to remove these sub-massive clots may have long-term adverse events including recurrent PE, chronic

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pulmonary hypertension, and death. Up to 22% of these patients will die within 90 days. The EKOS EkoSonic® System provides a new life saving therapy for these patients. Until now, drugs were the only approved treatment.

Prof. Nils Kucher from the University Hospital of Bern (Switzerland), principal investigator of the Ultrasound Accelerated Thrombolysis of Pulmonary Embolism (ULTIMA) trial launched in 2010, emphasized, "Because the EKOS system incorporates into the catheter body small ultrasound transmitters which condition the clot to more rapidly absorb the thrombolytic drug, it can dissolve the clot faster than thrombolytic drug alone.

Dr. Tod Engelhardt, cardiothoracic surgeon from East Jefferson General Hospital (New Orleans, LA) added that, "Faster response with less thrombolytic drug means patients may recover within hours and the risk of bleeding is substantially reduced." I've treated 30 patients with the EKOS system. All have done remarkably well and I know we have saved lives. The patients treated were all in serious condition and within a few hours of commencing treatment were asymptomatic."

Dr. Peter Lin, vascular surgeon from Baylor College of Medicine (Houston, TX) commented, "There are frustratingly few tools available today to help the seriously ill patient with pulmonary embolism. Having now treated over 35 PE patients with the EKOS system within the past 2 years, I have adopted EKOS as our standard of care; a valuable addition to our armamentarium for pulmonary embolism."

Robert W. Hubert, President/CEO concluded that, "Since 2004, the EKOS system has been cleared for use by the U.S. FDA and European authorities for use in clearing blood clots in the arms and legs. EKOS pursued CE Mark for treating PE based on receiving positive results from physicians treating these patients with the EkoSonic® system, along with several centers publishing their findings in peer reviewed journals."

About EKOS Corporation: EKOS Corporation pioneered the development and clinical application of ultrasound infusion technologies in medicine, introducing its first system for the treatment of vascular thrombosis in 2005. Today, interventional radiologists, cardiologists, cardiothoracic and vascular surgeons at leading institutions around the world use the EKOS EkoSonic® Endovascular System to provide faster, safer and more complete dissolution of thrombus. The EkoSonic System is FDA-cleared for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. Visit www.ekoscorp.com.

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