



PRESS RELEASE

May 4, 2021
Gothenburg

XVIVO submits 510(k) file with US FDA for Kidney Assist Transport

XVIVO has submitted a 510(k) file with the US FDA for Kidney Assist Transport with the goal of receiving market clearance in the US later this year.

Following the announcement of XVIVO's acquisition of Organ Assist B.V. 1 October 2020, the 510(k) submission of its kidney perfusion machine, Kidney Assist Transport, is an important milestone for XVIVO towards establishing a commercial presence within abdominal transplantation in the US.

The Kidney Assist Transport is XVIVO's transportable organ preservation system designed for kidneys. The system enables isolated hypothermic oxygenated perfusion of the donor kidney during transportation from donor to recipient during the transplantation procedure.

According to the WHO, kidney disease is the world's tenth most common cause of death. Patients suffering from chronic kidney failure need regular dialysis or kidney transplant to survive. Transplantation is usually the best treatment as the patient avoids dialysis, pharmaceuticals and frequent medical check-ups. Dialysis is also a very costly life-sustaining treatment. In 2019, approximately 62,000 kidney transplants were performed from deceased donors worldwide. The United States is today by far the largest market with approximately 17,500 kidney transplants from deceased donors in 2019. The number of patients on the waiting list in the United States exceeds 90,000, so the need for organs available for transplantation far exceeds the supply.

"The submission of the 510 (k) file is an important milestone for XVIVO. The Kidney Assist Transport device is a unique product with the potential to transform the entire kidney transplant market by extending the life of kidneys and making more kidneys available for transplantation. In December a study was published in Lancet, where the outstanding clinical advantages of the Kidney Assist Transport with continuous oxygenated perfusion of kidneys were clearly demonstrated. It is therefore with great enthusiasm that we now, subject to regulatory clearance, look forward to launching the product on the American market, says Dag Andersson, CEO of XVIVO.

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About Us

Founded in 1998, XVIVO is the only medical technology company dedicated to extending the life of all major organs - so transplant teams around the world can save more lives. Our solutions allow leading clinicians and researchers to push the boundaries of transplantation medicine. XVIVO is headquartered in Gothenburg, Sweden, and has offices and research sites on two continents. The company is listed on Nasdaq and has the ticker symbol XVIVO. More information can be found on the website www.xvivoperfusion.com.

Attachments

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