

FDA approves lung preservation machine (Update)

August 12 2014

Federal health regulators have approved a novel device that can preserve donated lungs outside the body for possible transplantation into critically ill patients.

The Food and Drug Administration said Tuesday that the approval of the XVIVO Perfusion System could lead to more successful transplants of lungs for people with cystic fibrosis and other deadly respiratory diseases.

The device consists of a bubble-like chamber where the lungs are stored and connected to a series of pumps and filters that provide oxygen and a sterile cleansing solution. Lungs can be kept in the machine for four hours as doctors evaluate their suitability for transplant.

Only about one in five lungs currently donated meet the medical criteria for transplantation. By giving doctors more time to examine the organs, FDA officials say more lungs may ultimately be transplanted.

In 2012, 1,754 lung transplants were performed in the U.S. with 1,616 patients still on the national waiting list. Lung transplantation is often the only treatment for patients with end-stage lung diseases, including chronic obstructive pulmonary disease and idiopathic pulmonary fibrosis.

The device is made by Englewood, Colorado-based XVIVO Perfusion Inc.

The FDA approved the new device based on two studies of patients who received non-ideal lungs preserved with the XVIVO Perfusion System or ideal lungs preserved with conventional cold storage techniques. The studies showed that patients from both groups had similar survival rates up to a year after undergoing transplant.

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Citation: FDA approves lung preservation machine (Update) (2014, August 12) retrieved 13 May 2024 from <https://medicalxpress.com/news/2014-08-fda-lung-machine.html>

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