

FDA OKs HeartWare device for transplant patients

November 20 2012

The Food and Drug Administration on Tuesday approved a new heart pump for patients with severe heart failure who are awaiting a heart transplant.

Regulators approved HeartWare's Ventricular Assist System, a battery-powered device that is implanted in the chest, where it helps the heart's lower left chamber pump blood throughout the body.

The FDA has previously approved similar devices, known as ventricular assist devices, but HeartWare's device is smaller and may be easier to implant in some patients.

FDA says the approval was based on a company study of 137 advanced [heart failure patients](#) implanted with the device. Study results showed rates of adverse events, including infection and stroke, were similar to those seen with older devices.

Medical device maker HeartWare International Inc. is based in Framingham, Mass.

Copyright 2012 The Associated Press. All rights reserved. This material may not be published, broadcast, rewritten or redistributed.

Citation: FDA OKs HeartWare device for transplant patients (2012, November 20) retrieved 4 May 2024 from <https://medicalxpress.com/news/2012-11-fda-oks-heartware-device-transplant.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.