

FDA OKs first compact heart-assist device

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The U.S. Food and Drug Administration announced approval of a compact heart-assist device that's the first to be designed for a small-sized adult.

The FDA said the device mechanically supports the weakened heart of a person suffering heart failure who is at risk of dying while awaiting a heart transplant.

Heart-assist devices are surgically implanted mechanical pumps that help the heart move blood to the rest of the body. Previous models were too large to be placed in the upper abdomen of some women and small-sized men, the FDA said.

But the device approved Monday -- the Thoratec HeartMate II Left Ventricular Assist System -- employs a first-of-a-kind design. Instead of the standard pulsatile pump that simulates the action of the heart, the device uses a continuous flow pump that constantly moves blood with a single moving part, a spinning rotor.

The agency said that design allows the device to be slimmed down to a only 3 inches in length and a weight of approximately 1 pound.

The FDA said the product's manufacturer, the Thoratec Corp. of Pleasanton, Calif., is required to conduct a post-approval study to further evaluate the HeartMate II's performance during commercialization.

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