Approval expanded for sapien artificial heart valve

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(HealthDay)—U.S. Food and Drug Administration approval for the Sapien Transcatheter Heart Valve has been expanded to include additional people with aortic valve stenosis, the medical term for a narrowing of the aortic valve that prevents the valve from functioning properly.

The new approval sanctions the artificial valve for patients who are at above-average risk of complications from valve surgery, including the possibility of death, the agency said Friday in a news release. The valve was first approved in 2011.

The device is implanted without opening the chest. It is compressed and placed into a delivery catheter that's inserted through an artery in the leg and is threaded to the site of the diseased valve.

The replacement valve should not be implanted in people who cannot tolerate anti-clotting therapies, the FDA warned.

Device maker Edwards Lifesciences Corp, based in Irvine, Calif., will conduct ongoing studies to monitor the valve's performance among recipients, the agency said.

More information: To learn more about this condition, visit the American Heart Association.