

FDA: improved artificial heart valve approved

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(HealthDay)—The newest version of the Sapien 3 Transcatheter Heart Valve has been approved by the U.S. Food and Drug Administration.

The artificial valve is designed for patients with [aortic valve stenosis](#). The product is sanctioned for people who are inoperable or at high risk for death or complications from [open-heart surgery](#), the FDA said in a news release.

The newly approved device is the third-generation Sapien 3, originally approved in 2011. The newest version includes changes designed to minimize leakage, the FDA said. Possible side effects of the device itself include stroke, [acute kidney injury](#), heart attack, bleeding, the need for a pacemaker, or death.

The device isn't recommended for people who can't tolerate anticoagulation/antiplatelet therapy, the agency said. The Sapien 3 is

manufactured by Edwards Lifesciences, based in Irvine, Calif.

More information: [More Information](#)

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