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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