Breaking: FDA approves Edwards' Sapien TAVI system for lower-risk patients

Mass Device

Medical device giant Edwards Lifesciences wins expanded FDA approval to market its Sapien transcatheter aortic valve replacement systems to lower-risk patients.

Edwards Lifesciences [1] (NYSE:EW [2]) won FDA approval to market its Sapien transcatheter aortic valve implantation to lower-risk patients, despite concerns about limited patient data on the long-term side effects of the device.

The federal watchdog agency approved the Sapien TAVI system for use in patients who are eligible for surgery but who are "at high risk for serious surgical complications or death," according to the FDA notice.

Sapien late last year won FDA approval only in inoperable patients, and the device remains the only TAVI system approved for the U.S. market.

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