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FDA grants expanded use of Sapien 3 artificial heart valve for high-risk patients

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n both aortic and mitral valve-in-valve patients, the observed mortality rates were substantially lower than the expected mortality rate for repeat surgery.

Singapore - The U.S. Food and Drug Administration (FDA) approved an expanded use of the Sapien 3 Transcatheter Heart Valve (THV) for patients with symptomatic heart disease due to failure of a previously placed bioprosthetic aortic or mitral valve whose risk of death or severe complications from repeat surgery is high or greater.

Bram Zuckerman, M.D., director of the division of cardiovascular devices at the FDA's Center for Devices and Radiological Health said, "For the first time, a regulatory agency is approving a transcatheter heart valve as a valve-in-valve treatment when bioprosthetic mitral or aortic valves fail in patients who are at high or greater risk of complications from repeat surgery. This new approval offers U.S. patients with failing surgical bioprosthetic aortic or mitral valves a less-invasive treatment option."

There are various reasons for the failure of a bioprosthetic aortic or mitral valve. It may be due stenosis (valve narrows and causes the heart to work harder to pump blood) or regurgitation (valve does not close completely and blood leaks backwards), or a combination of both. A repeat open-heart surgery is required, which causes a high or greater risk of complications for certain patients.

The FDA evaluated data from the Transcatheter Valve Therapy Registry, a partnership of the American College of Cardiology and the Society of Thoracic Surgeons. The data reveals that more than 85 percent of patients who underwent aortic or mitral valve-in-valve procedures, experienced clinically meaningful improvement in their heart failure symptoms.

The FDA granted accelerated approval of Sapien 3 THV to Edwards Lifesciences LLC.