FDA approves innovative, non-invasive heart valve

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(AP) -- Federal health officials have approved a first-of-a-kind artificial heart valve that can be implanted without major surgery, offering a new treatment option for patients who are too old or frail for the chest-cracking procedure currently used.

The Food and Drug Administration said late Wednesday it approved Edwards Lifesciences' Sapien heart valve, which can be threaded into place through a major artery that runs from the leg up to the heart. Cardiologists say the highly anticipated new approach will help old, sickly patients who cannot undergo the more invasive open heart surgery, which has been used to replace valves for decades.

Other companies have won approval for less-invasive heart valves before, but Edwards' implant is the first replacement for the aortic valve, the heart's main doorway.

About 300,000 U.S. patients suffer from deterioration of the valve, which forces the heart to work harder to pump blood, often leading to heart failure, blood clots and sudden death. More than half of patients diagnosed with the condition, called aortic stenosis, die within two years, according to the FDA.

Every year about 50,000 people in the U.S. undergo open-heart surgery to replace the valve, which involves sawing the breastbone in half, stopping the heart, cutting out the old valve and sewing a new one into place. Thousands of other patients are turned away, deemed too old or ill

to survive the operation.

The Mayo Clinic's Dr. David Holmes said the Sapien valve is a "game changer" for those inoperable patients, many of whom are in their 80s with medical conditions like diabetes, emphysema and liver disease.

"We don't have very good therapy for them at this time - some of them receive palliative care and some receive medication," said Holmes, who is president of the American College of Cardiology. "But this is really a mechanical problem, and for mechanical problems medications don't work very well."

Edwards' transcatheter valve is threaded through the femoral artery via a small incision in the leg, and then guided up to the heart via catheter. The valve is then wedged into the aortic opening by an inflatable balloon, replacing the natural heart valve. The device is made from cow tissue and polyester supported by a steel frame.

FDA based its approval on a 365-patient study that compared outcomes for patients with the valve and those who received basic comfort care and other non-surgical treatment. After one year, 70 percent of patients with the valve were still alive, compared with only 50 percent of those who received alternatives. However, the device was associated with serious complications, including stroke and internal bleeding. Under the conditions of FDA approval, Edwards will track the medical history of all patients who receive the valve.

The device is only approved for patients who cannot undergo open-heart surgery.

About 20,000 new U.S. patients will be eligible to receive a heart valve each year based on Wednesday's approval, according to Morgan Keegan analyst Jan Wald.

The larger opportunity for the new valve is in patients who are healthy enough to undergo surgery, but are considered high-risk and could benefit from a less invasive procedure. The FDA is expected to clear the device for those patients next year, and analysts estimate that group could eventually number between 50,000 and 80,000 annually as the U.S. population ages.

Edwards is expected to charge about $30,000 for the valve, though hospital fees could bring the total cost of surgery closer to $70,000. Standard heart valve replacement costs upward of $50,000, mostly from surgical and hospitalization fees.

The approval represents a dramatic business opportunity for Irvine, Calif.-based Edwards Lifesciences Corp., which had total sales of $1.5 billion last year. Analysts estimate that sales of the Sapien valve could help double the company's revenue to $3 billion within a decade. Company shares rose $3.11, or 4.2 percent, to $77.48 in after-hours trading.

The company expects to train surgeons at 150 to 250 sites across the U.S. to implant the Sapien in the coming year.

The valve has already been approved for four years in 40 countries around the world, including most of Europe. In most of those countries Edwards already sells a next-generation version of the device.