FDA favors innovative heart valve for the frail

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The first artificial heart valve designed to be implanted without major surgery appears to help patients who are too frail to undergo chest-opening surgery, according to federal health reviewers.

The Food and Drug Administration posted its review Monday of a highly anticipated heart valve from Edwards Lifesciences that can be threaded into place through one of the body's major arteries. Cardiologists hope this approach could offer a new option for patients who aren't healthy enough to undergo the more invasive open-heart surgery, which has been used to replace valves for decades.

FDA says 20 percent more patients who received Edwards' valve were living after one year than patients who received traditional medical care. However, scientists also said patients receiving the device had higher rates of stroke and bleeding in the brain.

The agency will ask a panel of heart doctors to weigh in on these risks at a meeting Wednesday, though the agency is not required to follow the group's advice.

Edwards will eventually seek FDA approval to market its valve for patients who are healthy enough for open-heart surgery. But because the valve is an experimental therapy, it was initially studied for patients with no other options.

Some 300,000 Americans have a diseased aortic heart valve, forcing the

heart to work harder to squeeze blood through. Eventually the condition can lead to heart failure, blood clots and sudden death. More than 50,000 people a year undergo open-heart surgery to replace the valve, and thousands more are turned away, deemed too old or ill to survive the operation.

The surgery involves sawing the patient's breastbone in half, stopping the heart, cutting out the old valve and sewing a new one into place.

Edwards' Sapien transcatheter valve, which is already available in Europe, is threaded through a leg artery up to the heart and then propped open and wedged into the aortic opening, replacing the natural heart valve.

Edwards will make the case for approving its device based on a study that showed nearly 70 percent of patients with the valve survived at least a year, compared with only 50 percent of those without it. However, FDA reviewers point out that little is known about patient survival after two years and longer-term safety studies are still needed. By contrast, patients who receive heart valves through open-heart surgery have been documented to live for decades.

FDA raises concerns that neurological side effects were more than three times higher among patients with the Sapien valve than for patients in the control group. Fourteen percent of patients with the valve experienced stroke, hemorrhaging or other brain-related problems. That compared to just 4.5 percent of patients who did not receive the valve. The FDA says these problems were actually probably underreported, since patients were assessed by a cardiology team rather than doctors specializing in brain injury.

Regulators suggest the stroke risk should be further analyzed in a follow-up study - even if the valve is approved. Edwards has proposed giving

patients in that study a regimen of blood thinners to help reduce stroke risk.

If approved, 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.

Shares of Irvine, Calif.-based Edwards Lifesciences Corp. rose 39 cents to $89.33 in morning trading.