Medtronic gets OK to study heart valve in US

The Associated Press

Medtronic Inc., the world's largest medical device maker, said Friday it received U.S. regulatory approval to begin testing a new artificial heart valve that can be implanted with minimal surgery.

The company said the Food and Drug Administration gave clearance to study the company's CoreValve system in the U.S. The product has already been implanted in 12,000 patients abroad.

The CoreValve implant is designed to be snaked through a major artery and fitted into place without the open-heart surgery typically required for implanting a new heart valve. The product is seen as an important option for patients too old or frail to undergo open-heart surgery.

Competitor Edwards Lifesciences pioneered the technology and is on target to gain FDA approval for its Sapien valve late next year.

Wells Fargo analyst Larry Biegelsen wrote in a note Friday that Medtronic's valve probably won't gain U.S. approval until late 2014 at the earliest.

Some 300,000 Americans with seriously diseased aortic valve could benefit from the procedure. When the aortic valve — a flap that controls blood flow to the heart — decays until it can't open properly, that forces the heart to work ever harder to squeeze blood through. 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 arduous operation.

Shares of Medtronic Inc. rose 8 cents Friday to $33.35 in morning trading.

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