Medtronic heart device has safety issues: FDA staff

U.S. reviewers said a Medtronic Inc device was effective for treating a common heart rhythm disorder, but they raised concerns about its safety.
Medtronic's Cardiac Ablation System is designed to treat persistent atrial fibrillation, a major cause of strokes. But, in documents released on Tuesday, Food and Drug Administration staff expressed concerns about the high rate of stroke found in patients treated with the device.

Atrial fibrillation, which affects more than 2 million Americans, is the most prevalent heart rhythm disorder. It describes the rapid and irregular contraction of the heart's upper two chambers, which allows blood to pool. This can form clots that travel to the brain and cause strokes.

Medtronic is seeking approval for the device as a treatment for persistent atrial fibrillation, which lasts for more than seven days or recurs for as long as four years. The company said just over half of patients have persistent atrial fibrillation, but there are no FDA-approved devices to treat this condition.

In a clinical trial, five people out of 176 had a stroke within a month of getting the Medtronic device, and 38 people had at least one serious problem such as low blood pressure or swelling of the covering around the heart, FDA reviewers said.

The device helped some people in clinical trials; 55.8 percent of patients had regular heartbeats within six months of using Medtronic's device, compared to 26.4 percent of patients who used the typical treatment of anti-arrhythmic drugs to treat atrial fibrillation.

A panel of outside experts will consider the device at a meeting on Thursday, with the FDA set to make a final decision.

Given the FDA's safety concerns, Sanford Bernstein analyst Derrick Sung said he sees a 50 percent chance of the panel recommending the device for approval.

"We would emphasize that investor expectations are low," Sung said in a research note.

Anti-arrhythmic drugs such as beta-blockers can help restore a normal rhythm. However, Medtronic and other companies such as Johnson & Johnson and Boston Scientific are turning to ablation devices to treat atrial fibrillation.

While such ablation devices are still a relatively small part of the multibillion atrial fibrillation market, analysts expect it to grow.

Ablation is a non-surgical technique used to neutralize the cells within the heart muscle that are responsible for starting or maintaining these abnormally fast, and sometimes lethal rhythms.

The Medtronic device uses catheter ablation, which involves inserting a thin tube into a blood vessel, usually through a site in the upper leg or neck, then threading it though the body until it reaches the heart.

When it reaches the area causing abnormal rhythms, a device emits radiofrequency energy to destroy the tissue.

Medtronic received FDA approval in December 2010 to sell a different ablation device for treating paroxysmal atrial fibrillation, which is intermittent -- meaning it lasts for less than seven days -- but recurring.

Medtronic shares fell 1.5 percent to $34.19 in trading on the New York Stock Exchange, below a 1.1 percent drop in the S&P Health Care Equipment index.

(Reporting by Anna Yukhananov in Washington; Editing by Gerald E. McCormick and Robert MacMillan [1])

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