Medtronic News

Medtronic Stent Graft Chosen by U.S. FDA for Innovative Program

Regulatory Agency Selects Investigational Medical Device for Endovascular Treatment of Thoracic Aortic Aneurysms Involving Branch Vessel for Early Feasibility Pilot Program

MINNEAPOLIS -- June 21, 2012 -- The U.S. Food and Drug Administration (FDA) recently selected a stent graft being developed by Medtronic, Inc. (NYSE: MDT) for an early feasibility pilot program that allows for "early clinical evaluation to provide proof of principle and initial clinical safety data."

One of nine devices selected for the program, the Valiant® Mona LSA system is a stent graft designed to repair a descending thoracic aortic aneurysm encroaching on the left subclavian artery (LSA). The device is based on the market-leading Valiant® Captivia® Thoracic Stent Graft, which is approved by the FDA for treating aneurysms/penetrating ulcers and related conditions of the descending thoracic aorta without major surgery.

"Endovascular repair of thoracic aortic aneurysms involving branch vessels represents a clinical and technological challenge that Medtronic is committed to solving for the benefit of physicians and patients alike," said Tony Semedo, vice president and general manager of the company's Endovascular Therapies business. "In fact, about 40 percent of these cases involve coverage of the LSA -- and, therefore, often require surgical bypass to preserve blood flow to the posterior brain and left arm." "Our Valiant Mona LSA system could potentially obviate the need for LSA bypass procedures, extending the benefits of endovascular repair without surgery to more patients with thoracic aortic aneurysms," Semedo added. "We are pleased that the device was selected by the FDA for its early feasibility pilot program, which demonstrates the agency's understanding of the need for collaborative innovation."

In 2011, the FDA published a draft guidance document to encourage and facilitate early feasibility studies of innovative medical devices in the United States. The pilot program will help test and refine the new approaches described in the draft guidance, which can be found on the FDA website.

According to the guidance document: "An early feasibility study is a limited clinical investigation of a device early in development, typically before the device design has been finalized, for a specific indication (e.g., innovative device for a new or established intended use, marketed device for a novel clinical application). It may be used to evaluate the device design concept with respect to basic safety and device functionality in a small number of subjects (generally fewer than 10 initial subjects) when this information cannot be readily provided through additional nonclinical assessments or appropriate nonclinical tests are unavailable. Information obtained from an early feasibility study may guide device modifications."

A thoracic aortic aneurysm (TAA) is a dangerous bulge in the body's main artery near where it originates from the heart. When left untreated, a TAA can rupture, leading to an emergency situation in which extensive internal bleeding usually leads to death.

A thoracic stent graft is a tubular medical device that a physician delivers through a pre-loaded catheter inserted in the patient's femoral artery. Once deployed, the stent graft conforms to the wall of the aorta, the body's main artery, creating a new path for blood flow that reduces pressure on the aneurysm and the risk of rupture.

According to the Society for Vascular Surgery (SVS), an estimated 40 percent of patients with descending thoracic aneurysms have insufficient seal zones for endovascular repair. The seal zone is the circumferential length of healthy aorta required to secure the placement of the stent graft across the aneurysm. Published reports show a higher rate of stroke and mortality associated with coverage of the LSA. Based on these reported adverse events, the SVS has recommended routine pre-operative revascularization to perfuse the LSA in patients who need

elective endovascular repair where achievement of an adequate seal requires coverage of the LSA.

The international market leader in its product category, the Valiant Captivia Stent Graft is approved by the FDA for endovascular repair of aneurysms and penetrating ulcers of the descending thoracic aorta in patients with a non-aneurysmal aortic diameter in the range of 18-42mm and non-aneurysmal aortic proximal and distal neck lengths ≥ 20mm.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

ABOUT MEDTRONIC
Medtronic, Inc. (http://www.medtronic.com/), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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