Medtronic News

Medtronic Receives FDA Panel's Unanimous Recommendation for Approval of Revo MRI(TM) SureScan(TM) Pacing System

Positive Step Toward the First Pacemaker System Approval in the United States for Use in the MRI Environment
MINNEAPOLIS, Mar 19, 2010 (BUSINESS WIRE) -- Medtronic, Inc. (NYSE:MDT) today announced that the U.S. Food and Drug Administration (FDA) Circulatory System Devices Panel of the Medical Devices Advisory Committee has voted unanimously in favor of approval with conditions of the Revo MRI(TM) SureScan(TM) pacing system designed as MR Conditional, or safe for use in Magnetic Resonance Imaging (MRI) systems under specified conditions. MRI procedures are not recommended in the United States for patients who currently have implanted pacemakers; if approved, Revo MRI has the potential to be the first FDA-approved pacing system designed for use in the MRI setting.

The FDA's Circulatory System Devices Panel, which met today, recommended Revo MRI for approval with conditions related to the planned post-market study, health care professional training, and labeling to reflect MRI scans are to be conducted with the full Revo MRI SureScan Pacing System. The FDA will consider the panel's recommendation in its review of Revo MRI; however, it is not bound by its Advisory Committee's recommendations.

"MRI is critical in the diagnosis of many serious conditions; however, patients with current pacemakers most often do not have access to this vital technology," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "The result of today's panel brings Medtronic one step closer to helping address an important unmet patient need. We look forward to working with the FDA during the regulatory process so that we may provide certain pacemaker patients with access to MRI scans."

The number of MRI scans performed increases each yeari, as does the number of people with implanted cardiac devices.ii In 2007, there were approximately 30 million MRI scans conducted in the United States and that number continues to grow.iii It is estimated that more than 200,000 patients annually in the United States have to forego an MRI scan because they have a pacemakeriv due to the risks involved, including interference with pacemaker operation, damage to system components, lead or pacemaker dislodgement, heating of the lead tips and unintended cardiac stimulation.v,vi,vii,viii MRI scans allow physicians to make a wide range of health diagnoses by viewing highly detailed images of internal organs, blood vessels, muscle, joints, tumors, areas of infection and more.ix

The FDA panel reviewed safety and effectiveness data from a prospective, randomized multi center trial at 42 centers around the world featuring 464 implanted patients. Major inclusion criteria included standard Class I or II dual chamber pacemaker indication, which allowed for pacemaker-dependent patients. Patients were excluded if they had previously implanted medical devices or abandoned leads. Patients were randomized at implant to either receive an MRI or not to receive an MRI.

The primary endpoints evaluated were safety and effectiveness of the Revo MRI pacing system in the MRI environment. For safety, the MRI group was evaluated for MRI procedure-related complications through one month post MRI. The primary effectiveness endpoint tested equivalence between MRI versus control for atrial and ventricular pacing capture thresholds and atrial and ventricular sensed amplitudes through one month post MRI.

About Revo MRI(TM) SureScan(TM) Pacing System

Revo MRI was designed to address safety concerns around MRI procedures for patients who have implanted pacemakers. Revo MRI includes hardware modifications to the device and leads that are designed to reduce or eliminate several hazards produced by the MRI environment. In addition, since MRI scanners may cause traditional pacemakers to misinterpret MRI-generated electrical noise and withhold pacing therapy or deliver unnecessary pacing therapy, this new pacemaker includes a new SureScan feature that sets the device into an appropriate mode for the MRI environment.

The device and leads also contain radiopaque markers, viewable via X-ray, to indicate that the device is MR-Conditional. MR-

Conditional is a term used to indicate that a device may be used in the MRI environment under certain conditions, such as a particular type of MRI scanner and scanner settings.

About Medtronic

Medtronic, Inc. (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.

i IMV, "Benchmark Report: MRI 2007," IMV Medical Information Division 2008.

ii Zhan C, Baine WB, Sedrakyan , A, et al. Cardiac device implantation in the United States from 1997 through 2004: A population-based analysis. J Gen Intern Med 2008; 23(Suppl 1): 13-19.

iii IMV, "Benchmark Report: MRI 2007," IMV Medical Information Division 2008.

iv Medtronic calculations cited in Rod Gimbel and Ted McKenna, "Safety of Implantable Pacemakers and Cardioverter Defibrillators in the Magnetic Resonance Imaging Environment," Business Briefing: Long-Term Healthcare 2005 (2005) available at www.touchbriefings.com.

v Faris OP, Shein M. Food and Drug Administration perspective: Magnetic resonance imaging of pacemaker and implantable cardioverter-defibrillator patients. Circulation 2006;114:1232-1233.

vi Roguin A, Schwitter J, Vahlhaus C, et al. Magnetic resonance imaging in individuals with cardiovascular implantable electronic devices. Europace 2008;10:336-346.

vii Levine GN, Gomes AS, Arai AE, et al. Safety of magnetic resonance imaging in patients with cardiovascular devices: an American Heart Association scientific statement from the Committee on Diagnostic and Interventional Cardiac Catheterization, Council on Clinical Cardiology, and the Council on Cardiovascular Radiology and Intervention: endorsed by the American College of Cardiology Foundation, the North American Society for Cardiac Imaging, and the Society for Cardiovascular Magnetic Resonance. Circulation 2007;116:2878-2891.

viii Kalin R and Stanton MS. Current clinical issues for MRI scanning of pacemaker and defibrillator patients. PACE 2005;28:326-328.

ix American College of Radiology (ACR) and the Radiological Society of North America (RSNA). MRI of the body (chest, abdomen, pelvis). June 10, 2009. Available at http://www.radiologyinfo.org/en/info.cfm?pg=bodymr. Accessed March 11, 2010.

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