# Symplicity(TM) Renal Denervation System One of First Devices Accepted to Participate in Concurrent Review for Joint FDA Premarket Approval and Medicare National Coverage Determination

The Associated Press

*FDA-CMS Parallel Review Program Designed to Enable Efficient and Earlier Patient Access to Innovative Medical Advancements*

MINNEAPOLIS - March 6, 2013 - Medtronic, Inc. (NYSE: MDT) today announced the U.S. Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) have accepted the inclusion of the Symplicity(TM) renal denervation system for treatment-resistant hypertension in their parallel review program, which will allow CMS to begin consideration for national coverage determination while the FDA completes its review of safety and efficacy. The Symplicity renal denervation system currently is only available for investigational use in the United States.

The Symplicity renal denervation system is one of the first medical devices to participate in the pilot program for concurrent review designed to facilitate the development of innovative new products and increase the efficiency of the review processes for both agencies. The two federal agencies accepted the Symplicity renal denervation system into the parallel review pilot program through a selection process that is limited to a few innovative devices per year.

The parallel review will be based primarily on results from Symplicity HTN-3, Medtronic's U.S. clinical trial of the Symplicity renal denervation system for treatment-resistant hypertension. In August 2011, the FDA approved Symplicity HTN-3, allowing Medtronic to become the first company to conduct a randomized, controlled trial of renal denervation in the U.S.  Enrollment in this study is ongoing expected to be complete by the summer of 2013.

"We are pleased that FDA and CMS have accepted the Symplicity renal denervation system for parallel review. This joint review represents a significant step forward in accelerating patient access to renal denervation in the U.S.," said Sean Salmon, Senior Vice President and President, Coronary and Renal Denervation, Medtronic. "We look forward to working with both agencies to ensure an efficient and timely review so that we may offer a new treatment option for the millions of people with treatment-resistant hypertension in the U.S."

Symplicity HTN-3 is a single-blind, randomized, controlled trial designed to evaluate the safety and effectiveness of renal denervation with the Symplicity renal denervation system in patients with drug-resistant hypertension. The study will randomize 530 patients in up to 90 U.S. medical centers; patients in the clinical trial

will be randomized to receive either renal denervation and treatment with anti-hypertensive medications or treatment with anti-hypertensive medications alone. The primary endpoints of the study are the change in blood pressure from baseline to six months following randomization and incidence of major adverse events one month following randomization. More information about Symplicity HTN-3 can be found at www.symplifybptrial.com.

Renal denervation therapy is a minimally invasive, catheter-based procedure that modulates the output of nerves that lie within the renal artery wall and lead into and out of the kidneys. The nerves passing to the kidneys are part of the sympathetic nervous system, which affects the major organs that are responsible for regulating blood pressure: the brain, the heart, the kidneys and the blood vessels.

ABOUT TREATMENT-RESISTANT HYPERTENSION
Treatment-resistant hypertension, defined as persistently high blood pressure despite three or more anti-hypertensive medications of different types including a diuretic, puts approximately 120 million people worldwide at risk of premature death from kidney disease and cardiovascular events such as stroke, heart attack and heart failure.[1],[2] Research suggests that nearly one third of treated hypertensive individuals are considered resistant to treatment.[3]

About the Symplicity(TM)Renal Denervation System
The Symplicity renal denervation system's catheter and proprietary generator and algorithms were carefully and specifically developed through years of clinical experience to accomplish the renal denervation procedure. The Symplicity renal denervation systemwas launched commercially in April 2010 and is currently available in parts of Europe, Asia, Africa, Australia, Canada and Latin America and has been used to treat thousands of patients with hypertension worldwide.

The Symplicity renal denervation system consists of a flexible catheter and proprietary generator. In an endovascular procedure, similar to an angioplasty, the physician inserts the small, flexible Symplicity(TM) catheter into the femoral artery in the upper thigh and threads it into both renal arteries in turn. Once the catheter tip is in place within the renal artery, the Symplicity(TM) generator is activated to deliver a controlled, low-power radio-frequency (RF) energy routine according to a proprietary algorithm aiming to deactivate the surrounding renal nerves. This, in turn, reduces hyper-activation of the sympathetic nervous system, which is an established contributor to chronic hypertension. The procedure does not involve a permanent implant.

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.

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.

[1] Egan, Brent M., et al. "Uncontrolled and Apparent Treatment Resistant Hypertension in the United States, 1988-2008."Circulation 2011;124:1046-1058.

[2] Hypertension and cardiovascular disease.World Heart Federation. 2011. http://www.world-heart-federation.org/ cardiovascular-health/cardiovascular-disease-risk-factors/hypertension/. Accessed January 23, 2012.

[3] Doumas, Michael, et al. "Benefits from Treatment and Control of Patients with Resistant Hypertension." International Journal of Hypertension 2011 (2011) Article ID 318549, 8 pages, 2011. doi:10.4061/2011/318549.