Medtronic News

Medtronic Completes Pre-Market Approval Submission to FDA for Arctic Front(R) Cardiac CryoAblation Catheter System

MINNEAPOLIS, Mar 17, 2010 (BUSINESS WIRE) -- Medtronic, Inc. (NYSE: MDT) today announced it has completed Pre-Market Approval (PMA) submission in consideration for U.S. Food and Drug Administration (FDA) approval for the Medtronic Arctic Front(R) Cardiac CryoAblation Catheter System, which is designed for patients with paroxysmal atrial fibrillation (PAF), an irregular quivering of the upper chambers of the heart that starts and stops on its own. Atrial fibrillation (AF) is the most common heart arrhythmia in the United States, with an estimated three million patients suffering from this condition.

The PMA submission includes data from the STOP AF (Sustained Treatment of Paroxysmal Atrial Fibrillation) pivotal clinical trial recently presented Monday, March 15 at the 59th Annual Scientific Session of the American College of Cardiology. The clinical trial evaluated the safety and effectiveness of the Arctic Front Cryocatheter System compared to anti-arrhythmic drug therapy.

Caution: The Medtronic Arctic Front Cardiac CryoAblation Catheter System is investigational and not currently available for sale in the United States. The device is limited by federal law to investigational use only.

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.

SOURCE: Medtronic, Inc.

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