

press release

June 13, 2012, 11:11 a.m. EDT

Cardiosolutions, Inc. Receives FDA 510(k) Clearance for Dexterity(TM) Steerable Introducer

Unique Co-Planar Steerable Introducer for Unrivaled Access to Cardiac Anatomy



PR Newswire
United Business Media

WEST BRIDGEWATER, Mass., June 13, 2012 /PRNewswire via COMTEX/ -- Cardiosolutions Inc., an emerging leader in structural heart solutions for valvular heart disease, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its Dexterity(TM) Steerable Introducer, a next generation structural heart access introducer and delivery conduit. The Dexterity(TM) Steerable Introducer is designed to provide physicians straightforward and uncomplicated access to the heart anatomy by simplifying the cardiac trans-septal procedure and facilitating passage of therapies into the entire left atrium, left ventricle and associated heart structures. The Dexterity(TM) Steerable Introducer is intended to be used for the advancement and delivery of various cardiovascular catheters into the heart, including the left side of the cardiac anatomy through the inter-atrial septum.

Dr. Thomas Piemonte, Chief Medical Officer for Cardiosolutions and Director, Interventional Cardiovascular Medicine and Cardiac Catheterization Laboratory at the Lahey Clinic in Burlington Massachusetts stated, "The Dexterity(TM) Steerable Introducer is an exciting, versatile product that permits unparalleled access to the heart chambers. We believe it is an ideal and essential tool for the Interventional or Electrophysiology physician who needs precise catheter placement with combined ease of use." Steven Tallarida, President and CEO of Cardiosolutions further offered, "The ability to generate revenue from our

Dexterity(TM) Steerable Introducer, while simultaneously advancing the development of our Mitra-Spacer(TM) technology shows our ability to create value early in the startup cycle. We now have a specialty introducer product that complements the development of the Mitra-Spacer(TM), a potential blockbuster device that is intended to mitigate mitral regurgitation."

Transcatheter therapy of structural heart disease is advancing rapidly. Due to the less invasive approach, transcatheter techniques have replaced surgery as standard procedure for a number of complicated interventional procedures. Evolving interventional techniques allow treatment of rhythm disorders, paravalvular leaks, ventricular septal defects and valve replacement. Until recently, therapy for these diseases was limited to patients in whom severe comorbidities lead to contraindications to surgery. Cardiosolutions Dexterity(TM) Steerable Introducer simplifies many of these procedures and could provide lower cost, less invasive procedures leading to superior patient results.

About Cardiosolutions, Inc. Cardiosolutions, Inc. ("Cardiosolutions" or the "Company") www.cardiosolutionsinc.com is developing a less invasive, percutaneous alternative to open heart surgical repair of the mitral valve. The Dexterity(TM) Steerable Introducer System and Mitra-Spacer(TM) could provide a long-term therapeutic substitute to this complicated open heart valve repair procedure. In this connection, it would address the unmet clinical need for a minimally invasive solution to the nearly 200,000 patients diagnosed annually with moderate to severe mitral regurgitation who currently forgo treatment because they cannot tolerate a highly invasive procedure. The Company is another novel medical device technology incubated within and spun out of STD Med, Inc. (Stoughton MA.) partnering with BioVentures Investors, a leading Medtech venture firm.

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