The Myxo File Part I and II helps to decode the mystery of the FDA 510(k) regulatory process

The Associated Press

/FROM PR NEWSWIRE DALLAS 888-776-3971/ [STK] [IN] [SU] -- WITH PHOTO -- TO NEWS EDITORS: The Myxo File Part I and II helps to decode the mystery of the FDA 510(k) regulatory process CHICAGO, Dec. 18, 2012 /PRNewswire/ - Understanding the regulatory issue surrounding the FDA 510(k) process may soon be a thing of the past thanks to a new book called The Myxo File: Part I and Part II just release through Kindle Direct Publishing. "The patients will understand what happened during their open heart procedure to repair their heart valve between 2006-2008." says author Nalini Marie Rajamannan M. D. Sacred Heart Cardiology, Chicago IL.

(Photo: http://photos.prnewswire.com/prnh/20121218/MM29659) "With the Myxo File Part I and Part II, the biographical story and the documents providing the evidence from the FDA, US Patent office and the United States Securities and Exchange Commission websites will help to explain the events that happened during the clinical study to test a new invention in the hearts of her patients during open heart surgery.

"My book will help to educate the patient ask the important questions prior to open heart surgery as to whether the device that will be used to repair their valve is FDA registered, cleared, approved, investigational or none of the above." Rajamannan was inspired to create the Myxo File when the documents she accumulated over a five year quest to get the information regarding the patients ended with a search of the US SEC website. The Filings indicate the chronology of disclosures of the medical device to investors. "With my electronic file, you still have to take action, and ask your physicians whether you are about to be included in a clinical study to test devices prior to FDA clearance, but at least the citizens of the United States will have a guidepost to help them ask the right questions.

Nalini M. Rajamannan is a cardiologist at Sacred Heart Cardiology, Sheboygan, WI, and Chicago, IL. She is the CEO of ConcieValve LLC, and recently published her textbook on Cardiac Valvular Medicine, Springer Publisher. She graduated from the University of Notre Dame, South Bend IN and Mayo Medical School and Mayo Graduate School, Rochester MN for all of her medical training. She is the chair of the recently published position statement from the NHLBI, NIH working group on Calcific Aortic Valve Disease. Dr. Rajamannan has published an International Clinical trial on the effects of statins in slowing the progression of aortic valve disease in the Journal of the American College of Cardiology with her colleagues from Spain and Portugal.

SOURCE ConcieValve LLC -0- 12/18/2012 /CONTACT: Kindle Direct Publishing: The Myxo File: Part I and Part II.
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