Bio2 Medical® Announces 510(k) Clearance from the FDA for the Angel® Catheter, the First Ever Prophylactic Use Indication for a Medical Device for Pulmonary Embolism

GOLDEN, Colo., Aug. 24, 2016 /PRNewswire/ -- Bio2 Medical is pleased to announce the Angel® Catheter has received 510(k) clearance from the United States Food & Drug Administration (FDA). This 510(k) clearance includes a first ever, prophylactic indication for a medical device to protect critically ill patients at high-risk for pulmonary embolism (PE) and contraindicated for anticoagulation. The Angel® Catheter provides a novel alternative to IVC filters for PE protection in a vast patient population that has historically been underserved. The device is designed for bedside placement, without the need for fluoroscopic guidance, and is designed to be safely retrieved in all cases once no longer indicated. The Angel® Catheter features a temporary Inferior Vena Cava (IVC) filter that is permanently attached to a Central Venous Catheter (CVC), and has been designed to reduce the rates of PE-related morbidity and mortality by trapping clinically significant pulmonary emboli. The Angel® Catheter is now commercially available in the U.S. The entire team at Bio2 Medical is proud to provide physicians in the U.S. with a unique device that has the possibility of truly improving patient care and saving lives.

Dr. John G. Myers, Professor and Chief of the Division of Trauma and Emergency Surgery at the University of Texas Health Science Center in San Antonio, had this response to the news: "The approval for clinical use by the FDA for this device will significantly impact trauma care. The majority of pulmonary emboli occur in the first three to four days after injury. Being able to protect our patients from pulmonary embolism during this time period, which is also the time period where traditional chemoprophylaxis is frequently contraindicated, will be extremely beneficial. In addition, this device also obviates the significant long-term complications of the currently available indwelling vena cava filters which include migration, fracture, erosion and caval thrombosis, where the current removal rate is dismal."

Dr. John A. Kaufman, Director, Dotter Interventional Institute and Frederick S. Keller Professor of Interventional Radiology, Oregon Health & Science University Hospital, echoed these sentiments and provided the following statement: "This is an important advance in the care of high-risk patients that allows for bedside initiation of mechanical protection from pulmonary embolism with a truly temporary device that also provides vascular access."

Dr. Luis F. Angel, the inventor of the Angel® Catheter and Chief Medical Officer at Bio2 Medical, provided the following comment regarding the importance of Bio2 Medical's participation in the FDA's Early Feasibility Pilot Study Program: "The Early Feasibility Pilot Program was a great opportunity to formally introduce this device to the FDA and to understand their requirements and our vision for this product. It also provided us the possibility to evaluate this device in the United States in a research environment that is proven to be the most effective and scientifically sound. In the end, this process was very beneficial to introducing a new device with a new indication and also for the FDA in learning about future products early in their life cycle."

Christopher E. Banas, Chairman and Chief Executive Officer of Bio2 Medical, stated, "We are excited to enter into this new commercial phase and to have the opportunity to fulfill our company's mission to improve patient outcomes by offering our life-saving product to the American public. The transition to a successful and profitable company is fully underway with the hiring and training of a national direct sales team, led by Jeffrey Hutchison, our new Vice President of U.S. Sales. The achievement of U.S. FDA 510(k) clearance represents the successful culmination of a significant undertaking for Bio2 Medical, and we could not have done it without the faith, trust and support of our entire team, our Board of Directors and our investors who have tirelessly supported our dream and made this day possible."
For more information on Bio2 Medical and the Angel® Catheter, please visit www.bio2medical.com.

Source: http://www.prnewswire.com/news-releases/bio2-medical-announces-510k-clearance-from-the-fda-for-the-angel-catheter-the-first-ever-prophylactic-use-indication-for-a-medical-device-for-pulmonary-embolism-300317644.html

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