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BiO2 Medical's IDE Application for the Angel(TM) Catheter Receives FDA Approval

SAN ANTONIO, May 1, 2013 /PRNewswire/ -- BiO2 Medical, Inc., a Texas based medical device manufacturer with corporate offices in San Antonio, Texas, and R&D and manufacturing operations in Golden, Colorado, is among the first to receive U.S. Food and Drug Administration (FDA) approval of their Investigational Device Exemption (IDE) application to begin an Early Feasibility Pilot Study (EFPS) using the Angel(TM) Catheter.

The Angel(TM) Catheter is the first to combine the functions of an Inferior Vena Cava (IVC) Filter and a multi-lumen Central Venous Catheter (CVC) for the prevention of Pulmonary Embolism (PE), and for access to the central venous system. The device is designed to be placed in the inferior vena cava, at the patient's bedside, without the need for fluoroscopy. The Angel(TM) Catheter was the first IVC Filter to receive CE Mark approval for a prophylactic indication, in addition to traditional IVC Filter & CVC indications.

According to Christopher E. Banas, BiO2 Medical's Chairman and Chief Executive Officer, "With this program, the FDA's forward thinking approach will allow innovative technologies, like the Angel(TM) Catheter, to become available for patients in the U.S. in a more expeditious manner."

The clinical investigation is being conducted as part of a new FDA program, the Early Feasibility Pilot Study Program. BiO2 Medical, Inc. is one of only nine U.S. based, medical device companies selected to participate.

The EFPS Program provides study sponsors (manufacturers), as well as FDA device reviewers', a foundation to establish criteria for device modifications and/or protocol development for subsequent clinical studies. The FDA's new approach to clinical studies will facilitate the development of safer, more effective products, while expediting their availability to the patients that need them.

According to John A. Kaufman MD, Director of the Dotter Interventional Institute, Portland Oregon, "The Early Feasibility studies are a welcome innovation that will allow physicians, industry, and the FDA to accomplish the shared goal of bringing new devices to Americans in an expeditious and safe manner. This is a great example of how close collaboration between industry and the FDA can lead to a vastly improved process and benefit our patients."

The primary objective of BiO2 Medical's EFPS clinical trial is to obtain continued insight into the safety of the Angel(TM) Catheter in critically ill patients with high risk of Venous Thromboembolism disease. For more information on BiO2 Medical's clinical studies, please visit http://www.bio2medical.com/news/.

SOURCE BiO2 Medical, Inc.

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