Endologix Submits Premarket Approval (PMA) Application to FDA for the *DETOURTM System.*

*FDA to Review First-of-Its-Kind Percutaneous Femoropopliteal Bypass System*

**IRVINE, Calif. October 10, 2022—**[Endologix LLC](https://endologix.com/), a privately held global medical device company dedicated to improving patients’ lives by providing disruptive therapies for the interventional treatment of vascular disease, today announced the submission of a Premarket Approval (PMA) application requesting approval for the ***DETOUR System*** to the U.S. Food and Drug Administration (FDA).

The DETOUR System, which earned FDA Breakthrough Device Designation, is a unique therapy that allows the creation of a fully percutaneous femoropopliteal bypass that is routed through the femoral vein. The DETOUR System uses the ENDOCROSSTM Device and TORUSTM Stent Graft to treat patients with moderate to severe peripheral arterial disease with long blockages of the superficial femoral artery.

The PMA application includes the results of the DETOUR2 IDE study, which were presented at the 2022 Annual Meeting of the Society for Vascular Surgery this past June. Dr. Sean Lyden, one of the study’s principal investigators presented results that included 12 month primary patency of 72.1% in SFA lesions with a mean length of 32.7cm. The trial demonstrated technical success of 100% in 202 patients with a 30-day Major Adverse Event Rate of 7%.

“This submission is a significant milestone in our mission to expand our therapeutic products into the large peripheral vascular market opportunity. Patients with long SFA blockages have compromised treatment options at present due to high rates of failure with conventional endovascular techniques and the morbidity associated with open femoropopliteal bypass surgical procedures,” said Matt Thompson, MD, President, and CEO of Endologix. “Once approved, offering a fully percutaneous femoropopliteal bypass, will provide a disruptive, innovative therapy to physicians for the treatment of long-segment SFA disease and expand the treatment options available for these patients.”

**About Endologix**  
Endologix LLC is a California-based, global medical device company dedicated to improving patients’ lives by providing innovative therapies for the interventional treatment of vascular disease. Endologix’s therapeutic portfolio includes a variety of products in various stages of development that are designed to treat diseases that currently have clinically relevant unmet needs. These products are designed to treat a wide spectrum of vascular disease from abdominal aortic aneurysms to lower limb peripheral vascular disease. Excellent clinical outcomes will be achieved through meticulous attention to product design, manufacturing, and training, all backed by industry-leading clinical evidence. Endologix’s current commercial EVAR products include the AFX®2 device and the ALTO® Abdominal Stent Graft System. Endologix became a private company, wholly owned by Deerfield Management, on Oct. 1, 2020. In April 2021, Endologix completed the acquisition of PQ Bypass, Inc., a privately held medical technology, adding the DETOUR System and TORUS Stent Graft to the Company’s product pipeline. The DETOUR System and the TORUS Stent Graft have not been approved for sale by any regulatory body. The DETOUR System is an investigational device, limited by United States law to investigational use.

The company has offices and manufacturing sites in Irvine and Santa Rosa, California. To learn more about Endologix, please visit http://www.endologix.com/.

**About Deerfield Management**Deerfield is an investment management firm committed to advancing healthcare through investment, information, and philanthropy. For more information, please visit [www.deerfield.com](http://www.deerfield.com/).

Except for historical information contained herein, this press release contains forward-looking statements, including statements regarding the regulatory approval for our DETOUR System under development. Forward looking statements are subject to risks and uncertainties and other factors that may cause actual results to differ materially from those expressed or implied. The forward-looking statements contained in this press release speak only as of the date of this press release and Endologix undertakes no obligation to update any forward-looking statements contained in this press release to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events.

**Media Contact:**

Sandy Prietto

949-595-7240

sprietto@endologix.com