

New Embolic Device for Tumor Treatment and Other Oncology Uses Given Nod by FDA to Start Pivotal Clinical Trial

Investigators look forward to evaluating the new device designed for simplicity, controlled delivery, and deep vessel filling

SALT LAKE CITY, UTAH, UNITED STATES , May 21, 2024 /EINPresswire.com/ -- Fluidx Medical Technology, Inc. announced today that the FDA has granted Investigational Device Exemption (IDE) approval to initiate the GPX Embolic Device Pivotal Clinical Trial. The objective of this trial will be to evaluate the safety and effectiveness of the GPX Embolic Device.

Embolization is a minimally invasive catheter-based procedure that blocks blood flow to targeted blood vessels and organs. Over \$3.5 billion per year is spent on embolic devices to treat tumors, internal bleeding, aneurysms, fistula, uterine fibroids, prostates, malformations, neurovascular bleeding, and other conditions throughout the body, but these devices can be difficult to prepare and deliver.



Post-embolization angiogram of the GPX Embolic Device filling a pelvic tumor (as featured on the cover of Journal of Vascular and Interventional Radiology, February 2024)

"The GPX Embolic Device will fill a void in our toolbox," said Dr. Michael Darcy, Professor of Radiology at Washington University in St. Louis and past president of the Society of Interventional Radiology. "Its simplicity, visibility, and distal reach will allow us to achieve deep tumor occlusion independent of delivery technique."

As many as twenty medical centers across the United States, Canada, and New Zealand will participate in the study, which will begin enrolling shortly.

"This study will further expand on the positive results we saw in our recent multi-center clinical



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trial,” stated Libble Ginster, President and CEO of Fluidx Medical Technology. “Clinicians need more solutions to meet diverse patient needs.” The results of that trial were recently published in the Journal of Vascular and Interventional Radiology (JVIR). In that trial, the GPX Embolic Device achieved 100% technical success and high

usability scores from physicians for ease of preparation, deliverability, and visibility.

About Fluidx Medical Technology:

Fluidx Medical Technology, Inc. is a Salt Lake City, Utah based company focused on developing GPX, ULTRA, and IMPASS embolic technologies with applications across peripheral vascular, interventional oncology, and neurovascular embolization.

GPX, ULTRA, and IMPASS Embolic Devices are under development, described and shown for research, educational, and engineering use only, and do not have marketing clearance or approval in any market at this time.

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