# Fluidx Completes Submission of Premarket Approval Application for the GPX® Embolic Device

*Final module of PMA application submitted to FDA for easy to use, controllable embolic*

SALT LAKE CITY, UT, UNITED STATES, July 24, 2026 /EINPresswire.com/ -- Fluidx Medical Technology, Inc., a clinical stage medical device company advancing its portfolio of embolic technologies, announced that it recently submitted to the U.S. Food and Drug Administration (FDA) the final module of its premarket approval application (PMA) for the GPX Embolic Device.

> “Completing the PMA submission for GPX is a significant milestone towards our mission to bring to market a new category of easy to use, controllable embolic gels”
>
> *Libble Ginster, CEO*

The final PMA module contained the results from the pivotal IDE clinical trial which enrolled one hundred and fourteen (114) patients at eighteen (18) sites across the United States, Canada, and New Zealand, and involved more than forty (40) investigators. During the trial, GPX was delivered through over twenty different microcatheter configurations, (spanning sizes from 1.9Fr (0.025”/0.63mm) to 2.8Fr (0.037”/0.93mm) outer diameters and lengths from 110 cm to 165 cm), demonstrating broad compatibility across a wide range of commonly used delivery devices.  Prior modules, already reviewed by FDA, contained the pre-clinical testing and manufacturing components of the submission.

“Completing the PMA submission for GPX is a significant milestone towards our mission to bring to market a new category of easy to use, controllable embolic gels that can treat the widest range of clinical conditions,” said Libble Ginster, CEO of Fluidx Medical Technology, Inc. “We were excited by the positive feedback we received during our clinical trial, and this application is a key step toward making GPX available to the broader clinical community.”

The Fluidx GPX Embolic Device is not approved or available for commercial distribution in the United States and may not be approved or available for sale or use in other countries. In the United States, Canada, and New Zealand, the device is being used under an Investigational Device Exemption (IDE) from the US Food and Drug Administration (FDA).

About Fluidx Medical Technology:

Fluidx Medical Technology, Inc. is a Salt Lake City–based medical device company advancing a portfolio of next-generation embolic technologies, including GPX, ULTRA, and IMPASS. The company’s mission is to develop a new category of easy to use, controllable embolic gels that can treat the widest range of clinical conditions, effectively occluding the smallest vessels up to the largest vessels. www.FluidxMedical.com

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