

Alucent Biomedical Receives Regulatory Approval for Second U.S. Clinical Study

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FDA Grants an Investigational Device Exemption for Trial Evaluating AlucentNVS Technology for Promoting the Maturation of Arteriovenous Fistulas

SALT LAKE CITY--(BUSINESS WIRE)-- **Alucent Biomedical Inc.** today announced that the U.S. Food & Drug Administration (FDA) granted an Investigational Device Exemption (IDE) for a U.S. clinical study of its AlucentNVS technology for promoting the maturation of arteriovenous fistulas (AVF) in patients requiring hemodialysis. The milestone follows Alucent's first IDE approval from the FDA, which was granted in August 2023.

AlucentNVS combines an intravascular device with a photochemical process to link structural proteins in the wall of a blood vessel to control vascular remodeling. The intervention is designed to promote patency of the vessel's lumen and establish sustained improvement of blood flow. AlucentNVS is also designed to retain the natural functionality and flexibility of the vascular wall.

The company aims to improve the success rate of AV fistula maturation by utilizing its AlucentNVS technology in the surgical AVF creation procedure. This procedure is the gold standard for hemodialysis access for most patients; however, as many as 30-60% of AVFs fail to mature into conduits capable of supporting dialysis.

"This second IDE approval by the FDA will allow us to advance our goal to offer physicians and patients a more successful approach to initiating hemodialysis through an AVF in patients with kidney failure, a life-saving procedure where failure rates are still unacceptably high," said Dr. Myles Greenberg, CEO of Alucent Biomedical. "We believe our technology has the potential to transform the current standard of care for patients requiring dialysis."

The Activate AVF feasibility trial is already underway and enrolling patients at sites in Australia and Poland.

About Alucent Biomedical

Alucent Biomedical Inc. is a privately held company dedicated to developing and commercializing its revolutionary **AlucentNVS** technology for the treatment of patients requiring life-saving vascular procedures. Alucent Biomedical was founded by the Avera Research Institute, part of the multistate Avera Health System, in 2017. For more information, please visit [alucentbiomedical.com](https://www.alucentbiomedical.com), or find us on **LinkedIn**.

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