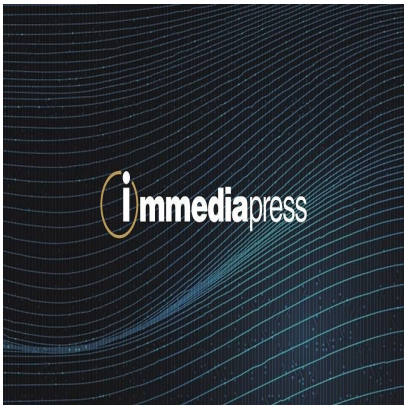

Bridge to Lifeâ?¢ Secures FDA De Novo Clearance for VitaSmartâ?¢ Hypothermic Oxygenated Perfusion (HOPE) System, the First Device Cleared in the U.S. for Hypothermic Oxygenated Perfusion of Donor Livers

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

FDA-cleared labeling supports broad clinical applicability, including Donation after Circulatory Death (DCD) donors, and positions VitaSmartâ?¢ as a scalable and economically compelling platform for U.S. transplant centers

DULUTH, Ga., Jan. 20, 2026 /PRNewswire/ â?? Bridge to Lifeâ?¢ Ltd., a global innovator in organ preservation and perfusion technologies, today announced that the U.S. Food and Drug Administration (FDA) has granted De Novo clearance for the VitaSmartâ?¢ Hypothermic Oxygenated Perfusion (HOPE) System, establishing a new regulatory classification for hypothermic oxygenated perfusion in liver transplantation in the United States.

The FDA clearance enables the commercial use of VitaSmartâ?¢ for hypothermic oxygenated perfusion of donor livers following static cold storage and prior to transplantation, providing a clear, regulated pathway for U.S. transplant centers to incorporate HOPE protocols into clinical practice.

â??This clearance represents a transformational milestone for Bridge to Life and an important advancement for liver transplantation in the United States,â?• said Don Webber, CEO and President of Bridge to Lifeâ?¢ Ltd. â??VitaSmartâ?¢ is the first FDA-cleared hypothermic oxygenated perfusion system for liver transplantation, and the labeling reflects FDAâ??s determination of safety and effectiveness, aligned with real-world transplant practice. We believe this will support adoption, contribute to improved organ utilization, and offer meaningful clinical and economic value to transplant programs.â?•

Expanding the Opportunity for DCD Liver Utilization

DCD donors represent one of the most significant opportunities to expand the available donor pool in liver transplantation. Inclusion of DCD grafts within the FDA-cleared labeling reflects the growing clinical

focus on preservation strategies designed to support graft conditioning prior to implantation.

â??Having an FDA-cleared hypothermic oxygenated perfusion system commercially available represents an important development for transplant programs,â?• said Kristopher Croome, MD, Professor of Surgery and Transplant and Hepatobiliary Surgeon at Mayo Clinic Florida. â??The availability of VitaSmartâ??s HOPE technology under FDA-cleared labeling, supports ongoing efforts to optimize preservation strategies, particularly with DCD liver grafts.â?•

Labeling Designed to Support Real-World Clinical Practice

The FDA-cleared labeling for VitaSmartâ?¢ supports hypothermic oxygenated perfusion of donor livers prior to transplantation in both Donation after Brain Death (DBD) and Donation after Circulatory Death (DCD) donors, within defined donor criteria.

Importantly, the cleared indication does not specify a maximum machine perfusion duration, allowing clinicians to apply hypothermic oxygenated perfusion within the scope of the indication using clinical judgment and established protocols.

Within the scope of the cleared labeling, VitaSmartâ?¢:

Together, these attributes position VitaSmartâ?¢ as a commercially scalable and economically compelling platform capable of broad adoption across U.S. transplant programs without adding unnecessary operational complexity or cost.

Clinical Evidence Supporting De Novo Clearance

FDA clearance was supported by data from the Bridge to HOPE pivotal clinical trial, a multicenter, randomized controlled study conducted in the United States evaluating end-ischemic portal venous hypothermic oxygenated perfusion in adult liver transplantation.

The study enrolled 219 recipients across 15 U.S. transplant centers, including extended-criteria donor populations in both DBD and DCD grafts. The statistically significant clinical results of the trial formed the basis for FDAâ??s De Novo determination and demonstrated improvements in early graft function with a strong safety profile.

Economic and Operational Considerations for Transplant Centers

Within the scope of its cleared use, VitaSmartâ?¢ is designed to support:

These considerations are increasingly important as transplant programs balance clinical outcomes, operational complexity, and resource constraints. Potential economic and operational benefits may vary by center and clinical practice.

Purpose-Built HOPE Technology for U.S. Adoption

VitaSmartâ?¢ delivers hypothermic oxygenated perfusion by cooling donor livers to controlled hypothermic temperatures while providing oxygenated perfusate prior to transplantation. The system is engineered for reliability, simplicity, and ease of use, supporting adoption across a wide range of transplant center environments under its FDA-cleared indication.

Acknowledgment of Investigators and Team

â??I want to personally thank the investigators, transplant teams, and clinical staff who participated in the Bridge to HOPE study, as well as the Bridge to Life team whose dedication and scientific rigor made this milestone possible,â?• added Webber. â??This clearance reflects years of disciplined clinical execution and collaboration, and we are deeply grateful to everyone who contributed.â?•

About Bridge to Lifeâ?¢ Ltd.

Bridge to Lifeâ?¢ Ltd. is a global leader in organ preservation solutions, offering a comprehensive portfolio that includes Belzer UWÂ®, EasiSlushÂ®, and the VitaSmartâ?¢ Hypothermic Oxygenated Perfusion System. Bridge to Life partners with transplant centers and organ procurement organizations worldwide to advance preservation science and support life-saving transplantation.

For more information, visit www.bridgetolife.com.

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