

OBVIUS Robotics™ Receives U.S. FDA Breakthrough Device Designation for CERTA™ Access System for Central Venous Catheterization

Sunrise, FL (August 26, 2024) – Obvius Robotics, a medical device company developing an innovative technology platform for democratizing vascular access, today announced the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for its CERTA Access System for central venous catheterization (CVC).

Breakthrough Device Designation expedites the review of innovative technologies that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. To qualify for a Breakthrough Device Designation, a device technology must show that it has the potential to provide more effective treatment than current standards of care. The goal of the program is to help patients have more timely access to these medical devices by expediting their development, assessment and review.

CVC procedures are performed over 20 million times per year globally, yet outcomes are varied dependent upon the training and experience of the clinician. The procedure involves gaining access to one of the great veins (internal jugular, subclavian, or femoral) to place a multi-lumen catheter for rapid replacement of blood volume, administration of emergency medicines and analgesics, and hemodynamic monitoring. Complication rates vary significantly, ranging from 4% to 11%, underscoring a significant need for better and more consistent outcomes.

“CVC procedures are required for a wide variety of conditions and patients for life saving care every single day,” said William Cohn, MD, Chief Medical Officer for Obvius Robotics. “Despite this fact, the procedure still has high complication rates and many health systems lack the expertise to reliably conduct the procedure on critically ill patients in a timely manner. A breakthrough is truly needed to improve care.”

“The goal of Obvius Robotics is to become the new standard of care for CVC access,” said Russell Seiber, President and CEO of Obvius Robotics. “We are excited that the FDA has recognized the potential of the CERTA Access System to be a breakthrough for patients and clinicians. We believe this technology could improve care critical care settings by democratizing vascular access procedures.”

The CERTA Access System is not approved for clinical use at this time, but the company is currently preparing its submission to the FDA for market clearance leveraging the Breakthrough Devices Program.

About Obvius Robotics

Obvius Robotics is a privately held medical device company based in South Florida with clinical offices in the Center for Device Innovation at the Texas Medical Center, Houston, that is developing technology for image-guided access of structures within the body. The platform technology, the CERTA Access System, incorporates robotics and imaging to improve the accuracy, safety, and consistency of accessing targeted anatomy. The company's first clinical application is central venous catheter placement, a high-volume procedure in which CERTA has the potential to aid clinicians of varying levels of training and experience in safely and effectively achieving vascular access. Note: The CERTA Access System is not approved or cleared for use in patients in any geography at this time.

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