

OBVIUS Robotics™ Completes First U.S. Cases with CERTA™ Access System

Fort Lauderdale, FL (September 4, 2025) – Obvius Robotics, a medical device company developing an innovative technology platform for precision access procedures, today announced that it has successfully completed the first cases with patients in its pre-market clinical study in the United States.

The company has developed the CERTA™ Access System, a handheld robotic platform for image-guided procedures requiring precise needle access to anatomical structures. The U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for this device, which is initially being targeted for vascular access procedures.

The first clinical cases were performed at the Texas Medical Center at Baylor St. Luke's Medical Center and at Northwell Health in New York. "Our critical care team recently performed its first central venous catheterization procedure successfully with CERTA," said Dr. Mangala Narasimhan, Director of Critical Care Medicine at Northwell Health. "This is a procedure that today is very manual and requires a highly skilled operator, and CERTA automates precise needle placement in a way that can democratize care."

The CERTA Access System combines ultrasound guidance with robotic needle placement. Its proprietary needle vibration technology reduces the movement and deformation of soft tissue during insertion, offering the potential for unmatched precision to the pre-selected target tissue.

"There are over 100 million vascular access procedures performed each year around the world," said Dave Herrmann, President and CEO of Obvius Robotics. "These procedures require significant expertise and still have high complication rates. We believe CERTA can solve both of these challenges, by offering expert-level precision for any operator, regardless of their experience, at the push of a button."

Upon completion of the clinical study, the company plans to submit CERTA to the FDA by the end of 2025, with approval in the United States anticipated in 2026.

"There have not been significant advances in vascular access technology or clinical outcomes for years," said Dr. Mourad Senussi, Director of the Cardiac Intensive Care Unit at Baylor and the Texas Heart Institute at Baylor College of Medicine. "By combining robotics with image guidance and needle vibration, we now have a new

paradigm that could become the new standard of care in both ease-of-use and outcomes in these procedures.”

About Obvius Robotics

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

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