



Reverse Medical Corporation Receives US FDA 510k Clearance for the ReFlex™ Catheter for Distal Intracranial Access

IRVINE, Calif. --(Business Wire) -- Reverse Medical Corporation announced today that it has received US FDA 510k clearance to market the ReFlex™ line of intracranial catheters for distal neurovascular access and microcatheter therapeutic delivery. The ReFlex Catheter is uniquely designed to provide endovascular intracranial access during interventional neurovascular procedures. The 510k allows the Company to market ReFlex™ Catheter in the United States.

The ReFlex™ Catheter provides the neurovascular specialist with a line of advanced access devices that can navigate into complex neurovascular anatomy, which may enable them to treat more patients than with currently available devices.

Dr. Satoshi Tateshima MD D.M.Sc, Associate Professor, Interventional Neuroradiology, Ronald Reagan UCLA Medical Center, Los Angeles, CA ([News](#) - [Alert](#)), stated, "The ReFlex Catheter performed beautifully in my recent challenging bifurcation aneurysm case. The large .072" lumen provided great contrast injection capability, with two micro catheter-systems in place. I could clearly visualize four MCA branches throughout the procedure, helping ensure a safe and highly effective clinical result."

Dr. Demetrius Lopes MD, Assistant Professor of Neurosurgery and Radiology at Rush Medical College, Rush University Medical Center, Chicago, Illinois stated, "My initial clinical cases with ReFlex went extremely well. One case in particular presented with very impressive anatomy to overcome, with excellent distal position enabling me to accurately place three Pipeline devices. The ability to simultaneously deliver Pipeline, coils and inject contrast through ReFlex is unprecedented."

Commenting on this regulatory approval, Reverse Medical's President and Chief Executive Officer, Jeffrey Valko said, "The clearance of ReFlex demonstrates that Reverse Medical truly understands the needs of the neurointerventionalist. The bar has been raised for achieving FDA 510k clearance, and the ReFlex clearance for commercialization represents a significant step forward for the growth of Reverse Medical. With our recently announced ReFlex CE Mark, this 510k now allows us to initiate worldwide commercialization. We believe the ReFlex Catheter line of devices will allow physicians to expand their therapeutic options for treating previously under-served patient populations." The Company plans to immediately commence US commercialization through direct sales support.

Reverse Medical Corporation is a privately-held medical device company focused on expanding the endovascular management of acute stroke and neurovascular disease. The technology platform includes innovative, state-of-the-art treatments for a broad spectrum of neurovascular disorders and carotid artery disease. The company is based in Irvine, California.