

DEVICE FOR PATIENTS WITH DYSPHAGIA GAINS FDA APPROVAL

ABOUT AMPCARE, LLC. Ampcare develops therapeutic neuromuscular electrical stimulation technologies, including the Ampcare ESP™ (Effective Swallowing Protocol), an innovative protocol for the treatment of dysphagia (swallowing difficulties). The Ampcare founders are committed to delivering positive patient outcomes and innovative products specially designed to meet the needs of the patient, medical professional and the payer. Ampcare's vision is to eliminate pneumonia and feeding tubes due to swallowing problems by improving the options and availability of dysphagia treatment techniques. Headquartered at TECH Fort Worth, Texas, Ampcare has three employees.

THE CHALLENGE. Ampcare applied for FDA clearance for their device, the Effective Swallowing Protocol, but the supplier of a key component, the powered muscle stimulator, was unable to meet the requirements for FDA clearance. Without this critical FDA-cleared component, Ampcare could go no further. TECH Fort Worth set up an initial meeting between Ampcare and TMAC, part of the MEP National Network™, to discuss the company's needs, and Ampcare decided TMAC was the right organization to assist in finding a new supplier or partner.

MEP CENTER'S ROLE. TMAC used Tech Scouting—a technique that originated by the Research Triangle International/Institute (RTI)—to conduct a supplier scouting project to find potential suppliers of the component. A key concern was for the potential supplier to be an FDA registered manufacturer of electrical muscle stimulators and to have successful experience in receiving FDA clearance of these devices. TMAC conducted the search and identified 69 potential suppliers or partners. Following Ampcare's criteria, the list was reduced to 11 potential suppliers. Ampcare selected three for TMAC to investigate more thoroughly. TMAC prioritized the list based on findings by the FDA, the size of the company, its history, and several other factors. Finally, TMAC forwarded contacts at the companies to Ampcare to start the negotiations and discussions.

After successfully engaging a supplier, Ampcare earned FDA approval for the Effective Swallowing Protocol, and entered markets in the UK, China, and Japan. The product is contributing to significant growth per net income for the company.

"As a specification developer, it was of great significance and value to find the right manufacturer to have a profound effect on the success of our medical device. We were grateful for the thorough Supplier Scouting search performed by Rich Bergs at TMAC as we were able to confidently proceed with a manufacturer and ultimately achieve FDA clearance for our product."

-Russ Campbell, PT and CEO

RESULTS



FDA-approved product



New markets in the UK, China, & Japan



55% growth in net income

CONTACT US



9390 Research Blvd., Ste.
11-300
Austin, TX 78759



(800)625-4876



www.tmac.org

