Catheter Robotics Announces FDA Approval

Catheter Robotics, Inc. is pleased to announce the additional 510(k) clearance by the Food and Drug Administration (FDA) of Amigo™ catheter for use with the EZ STEER™ diagnostic catheter handle made by Biosense-Webster. Catheter Robotics recently entered the US market with right-sided diagnostic approval for the diagnostic catheter, Blazer® DX – 20 catheter (Boston Scientific).

Amigo™ is a remote catheter system that allows physicians to operate a catheter up to 100 feet from the radiation field, allowing the physician protection from radiation. It is designed to be compatible with third-party catheters and to easily integrate into a hospital's existing electrophysiology lab. When placed on the Amigo system, the catheter is navigated by remote control that mimics the catheter handle, reducing the time needed for physicians to feel comfortable using a robotic catheter system.

"We are pleased to provide physicians with another catheter combination for Amigo. The wonderful thing about Amigo is that it is an open platform device, allowing the physician to select their preferred catheter. Having this approval should increase interest from physicians who use the Biosense-Webster EZ STEER™ catheters and help Catheter Robotics gain strength in the robotic market," said David Jenkins, President and CEO. "By allowing physicians to use the catheter of their choice, we are meeting a need that has not been met by other robotic companies."