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CardiacAssist, Inc. Wins FDA Approval for TandemHeart® Escort™ Controller

October 02, 2006, PITTSBURGH – CardiacAssist, Inc. has received FDA 510(k) market approval for its new TandemHeart® Escort™ Controller. The new, lightweight, space-saving Escort Controller is one of three primary components that make up the TandemHeart® PTVA® System. The TandemHeart System provides circulatory support through a cardiac catheterization procedure in as little as 30 minutes. It is FDA approved for extracorporeal support for up to six hours for procedures not requiring full cardiopulmonary bypass.

“Time can be a critical factor in providing extracorporeal circulatory support,” said Michael Garippa, President and CEO of CardiacAssist, Inc. “Regulatory approval of the new Escort Controller marks an important advancement for the TandemHeart System and a great success for the entire team at CardiacAssist.”

Weighing only 21 pounds, the Escort Controller replaces the original 93 pound TandemHeart Controller. It can be mounted at bedside, on an IV pole or on a table top. It is intended primarily for AC power use, but has enough battery back-up power for an hour of operation.

CardiacAssist, Inc. collaborated on the project with Minnetronix, a contract design and manufacturing company serving the medical device industry. “We are privileged to have partnered with CardiacAssist in developing of this innovative device,” said Richard Nazarian, President and CEO of Minnetronix.

The Escort Controller design retains proven subsystems that have been in use for years in the current controller, such as the pump motor drive circuits, flow estimator, air bubble detector, IV pump and infusion system. Retaining these subsystems maintains compatibility between the two generations of controllers and ensures a high degree of reliability.

The TandemHeart System is fully reimbursed by Medicare under existing DRG codes. It can be placed rapidly in the cath lab or operating room, providing reliable extracorporeal circulatory support via percutaneous access.

The TandemHeart System is used in 17 of the top 20 heart and heart surgery hospitals in the U.S. and 11 of the nation’s top 14 hospitals overall. To date, more than 700 uses of the system in 28 counties at 70 different facilities by 120 different physicians have been recorded. The TandemHeart System is the only FDA approved device of its kind in the U.S.

About CardiacAssist

Founded in 1996, CardiacAssist, Inc. is a privately held, Pittsburgh-based medical device company that develops, manufactures and markets innovative products designed to provide cardiologists and cardiac surgeons with minimally invasive solutions for providing extracorporeal circulatory support. Its vision is to help advance the treatment of heart disease by bridging gaps in current treatment methodologies.

CardiacAssist, Inc.

This press release may contain certain forward-looking statements that relate to CardiacAssist's future business and financial performance. Such statements are subject to a number of risks and uncertainties that may cause the actual events or future results to differ from those discussed herein.

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