# CardiacAssist receives FDA IDE approval for TandemHeart pivotal trial

Mass Device

The FDA gives CardiacAssist Investigational Device Exemption approval for a pivotal clinical study of the TandemHeart circulatory support system.

Pittsburgh-based medical device maker CardiacAssist received Investigational Device Exemption approval from the FDA to begin a pivotal clinical study of its TandemHeart circulatory support system.

The TandemHeart to Reduce Infarct Size trial will evaluate the effectiveness of ventricular unloading on the reduction of infarct size for patients with severe heart attack, according to the press release.