

# IEDC News

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## Medical Device Earns FDA Expedited Review

**INDIANAPOLIS** (Dec. 9, 2009) - FAST, a developer of medical testing technologies, announced today that the Food and Drug Administration has granted the company an expedited review of its technology for the rapid assessment of kidney function.

The company, which is a 2008 recipient of a \$2 million grant from the state's 21st Century Research and Technology Fund, is currently using the state funding and additional funding from the National Institutes of Health to prepare its early detection technology for further FDA review.

"Today's announcement is another step forward for an Indiana company that is developing potentially life-saving technology," said Mitch Roob, Secretary of Commerce and chief executive officer of the Indiana Economic Development Corporation. "The notice of an expedited review shows that the FDA has confidence in FAST's technology and that this company is right in line with the mission of the 21st Century Fund."

FAST's technology measures the body's kidney function, known as glomerular filtration rate, or GFR, by monitoring inert markers that have been injected into a patient's bloodstream. A fiber optic device inserted into a vein through a catheter tracks the markers, measuring how effectively the body filters waste giving an accurate filtration rate reading in only 40 minutes. There is currently not available any way to accurately and quickly measure GFR. Current estimates, which are not useful in Acute Kidney Injury, have accuracy limitations, and can take up to 24 hours for a reading.

FDA requirements for medical devices seeking an expedited review require that devices must treat or diagnose a life threatening or debilitating disease; and address an unmet medical need. The expedited status will allow FAST's documents and study results to receive priority during the approval process.

"Our team is thrilled with the expedited review status granted by the FDA," said Joe Muldoon, chief executive officer of FAST. "It was especially gratifying that the FDA determined we had demonstrated that this is 'breakthrough technology' that may provide a clinically meaningful advantage. This will help accelerate our pursuit of human trial data, and eventual market launch."

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