

FDA NEWS RELEASE

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FDA announces plans to pilot end-stage kidney disease technology in new program

Innovation Pathway aims to reduce time and cost of bringing safe and effective, breakthrough technologies to patients

Three products for patients with end stage renal disease (ESRD) have been chosen to participate in the FDA's Innovation Pathway, an evolving system designed to help medical devices reach patients in a safe, timely and collaborative manner.

The FDA selected three from 32 product applications ranging from an artificial kidney to devices that assist kidney function that were submitted in response to a January 2012 request from FDA's device center.

The three products are:

- An implantable Renal Assist Device (iRAD) being developed by the University of California, San Francisco.
- A Wearable Artificial Kidney (WAK) in development by Blood Purification Technologies Inc. of Beverly Hills, Calif.
- A Hemoaccess Valve System (HVS) that has been designed by Greenville, S.C.-based CreatiVasc Medical.

The majority of the 32 applications came from small, start-up business or academic institutions.

"The response from innovators exceeded our expectations and demonstrates that there is a desire from developers of innovative technologies for earlier and more collaborative agency interaction," said Jeffrey Shuren, M.D., director of the Center for Devices and Radiological Health (CDRH).

The ESRD products will be the focus of the second version of the Innovation Pathway, first announced in 2011, to shorten the time and cost it takes for the development, assessment and review of medical devices, in particular breakthrough medical devices.

ESRD is the progressive loss in kidney function over a period of months or years. The kidneys play an essential role, filtering and removing waste from the body and producing hormones that are responsible for calcium absorption and red blood cell production.

The FDA chose ESRD because more than half a million Americans suffer from the disease. Management of the disease is largely dependent upon medical device technology, such as hemodialysis (process for removing waste products) equipment. Most dialysis patients spend long hours in specialized outpatient clinics, impacting their quality of life and reducing productivity. Medicare alone covers some 75 percent of ESRD health care costs, which in 2009 topped \$29 billion.

"We found ESRD a natural fit given that patients have few options. We think this process could impact the lives of patients by providing access to innovative new technologies they so desperately need. In turn, this could also have a positive impact on health care, encouraging innovation through smarter regulation that could potentially save companies time and money," said Shuren.

Developers who participate in what FDA now calls Innovation Pathway 2.0 have an opportunity to collaboratively discuss their technology with FDA, work with the agency on the development of a benefit-risk

profile for their product that will help guide future studies and map out a regulatory path forward for their product.

This approach is intended to deepen collaboration between FDA and innovators early in the process, prior to pre-market submission, with the goal of making the regulatory and product development process more efficient and timely.

CDRH constructed the Innovation Pathway with help from the Entrepreneurs in Residence (EIR) program, which brings together professionals with diverse talents from inside and outside government to work together as a team on solution-oriented outcomes in a short and focused time frame. These outside experts worked alongside agency staff and leadership to address impediments to efficient and timely review processes and construct Innovation Pathway 2.0.

For more information:

[Innovation Pathway](#)

(<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/default.htm>)

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