FDA permits marketing of devices to create arteriovenous fistula

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(HealthDay)—The U.S. Food and Drug Administration has permitted marketing of two catheter-based devices designed to create an arteriovenous (AV) fistula in patients with chronic kidney disease in need of hemodialysis.

The devices are designed to create AV fistulas percutaneously; the AV fistulas are needed before patients can start hemodialysis. A catheter is inserted into a blood vessel in the arm and guided to the site of the planned fistula. The Ellipsys Vascular Access System and everlinQ endoAVF System use one and two catheters, respectively.

For the Ellipsys Vascular Access System, the FDA reviewed data from a study involving 103 patients. Three months after the procedure, 89.3 percent of the patients met the criteria for a usable AV fistula. To maintain the fistula, almost all patients (96.1 percent) required an additional procedure in the first 12 months. For the everlinQ endoAVF System, the FDA reviewed data from 60 patients in a multicenter study, as well as data from other studies. In the main study, 86.7 percent of patients met the criteria for a usable AV fistula within three months after the procedure. Overall, 96.7 percent of patients required an additional procedure at the time that the fistula was created.

"With today's action, there will be additional, less-invasive vascular access options for patients who will require hemodialysis," Bram Zuckerman, M.D., director of the Division of Cardiovascular Devices in the FDA's Center for Devices and Radiological Health, said in a statement.

More information: More Information