FDA Approves Two New AV Fistula Devices

The U.S. Food and Drug Administration (FDA) has granted marketing approval for two catheter devices used in dialysis. Both the everlinQ endoAVF System, which uses two catheters, and the Ellipsys Vascular Access System with a single catheter are designed to create arteriovenous (AV) fistulas, using an energy source to forge the connection between blood vessels in a patient's arm. Traditionally a central venous catheter for dialysis patients is created through a surgical process. An AV graft uses a tube or cadaveric blood vessel to create a bridge between artery and vein.

The FDA reviewed data for the everlinQ endoAVF System from a non-randomized, multi-center study of 60 patients, and also considered supporting data from three other studies. The device has been used by clinicians outside the United States.

TVA Medical (Austin, TX) manufactures the everlinQ system, which works as a series of spaced magnets in each catheter, one venous and one arterial, that are designed to attract and align. The patient is then ready for a radiofrequency pulse deployed at the desired spot between the close brachial (arm) blood vessels.

In the main study of the everlinQ endoAVF System, 52 patients (86.7%) met the criteria for a usable AV fistula within three months after the procedure. Almost all patients (96.7%) required an additional procedure at the time the fistula was created, and 28.3% of patients required an additional procedure (such as balloon angioplasty) in the first 12 months to maintain the fistula, the FDA noted.

The Ellipsys Vascular Access System is a product of Avenu Medical, based in San Juan Capistrano, CA. The single catheter delivers a small amount of thermal energy that fuses a permanent connection between the vein and artery.

The FDA reviewed data from a non-randomized, U.S. multicenter study of 103 patients, of whom 92 patients (89.3%) met the criteria for a usable AV fistula within three months. Almost all patients (96.1%) required an additional procedure (such as balloon angioplasty) in the first 12 months, the FDA reported.

Both systems were reviewed through the De Novo premarket review pathway for low-to-moderate risk devices of a new type.