

**K181725 Ellipsys Vascular Access System (Ellipsys System),
(Power Controller Model No. AMI-1001 & Catheter & Needle
Model No. AMI-6005)**Oct 5, 2018
98 days to decisionK181725 · Product code: **PQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k181725/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Catheter For Creation Of An Arteriovenous Fistula For Hemodialysis Access (PQK)
Date received	Jun 29, 2018
Decision date	Oct 5, 2018
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avenu Medical, Inc.
Location	San Juan Capistrano, CA, US
Contact	Rebecca K. Pine
510(k) history	3 submissions · 2 cleared · 2018-2019

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