

K183615 Ellipsys Vascular Access System (Ellipsys System), Power Controller, Ellipsys Vascular Access System (Ellipsys System), Catheter, Ellipsys Vascular Access System (Ellipsys System), Crossing NeedleJan 25, 2019
30 days to decisionK183615 · Product code: **PQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k183615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Percutaneous Catheter For Creation Of An Arteriovenous Fistula For Hemodialysis Access (PQK)
Date received	Dec 26, 2018
Decision date	Jan 25, 2019
Days to decision	30 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	Dave Campbell
510(k) history	3 submissions · 2 cleared · 2018-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183615/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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