

K191114 Ellipsys Vascular Access System (Ellipsys System), Power Controller, Ellipsys Vascular Access System (Ellipsys System), Catheter, Ellipsys Vascular Access System (Ellipsys System), Needle

Aug 9, 2019
105 days to decision

K191114 · Product code: **PQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k191114/>

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	Apr 26, 2019
Decision date	Aug 9, 2019
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avenu Medical
Location	San Juan Capistrano, CA, US
Contact	Dave Campbell
510(k) history	1 submissions · 1 cleared · 2019-2019

CLINICAL EVIDENCE - NCT02363972

Percutaneous Less Invasive AV Fistula for Vascular Access in ESRD

Status	Completed
Enrollment	103 patients (actual)
Study sites	5 sites
Condition studied	End Stage Renal Disease; AV Fistula; Fistula; End Stage Kidney Disease
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 1, 2016
Sponsor	Medtronic Endovascular (Industry)

Primary outcome

Maturation Success Rate at 90 Days

Secondary outcome

Percent of Participants With Access Systems That Successfully Created an AVF

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02363972