

K183179 CAPERE Thrombectomy SystemFeb 25, 2019
101 days to decisionK183179 · Product code: **QEW** · Cardiovascular
Source: <https://www.510kdatabase.net/k183179/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Nov 16, 2018
Decision date	Feb 25, 2019
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vascular Medcure, Inc.
Location	Anaheim, CA, US
Contact	Jeffrey P. DuMontelle
510(k) history	5 submissions · 5 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice M. Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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