

K182897 Velano Vascular Q2 Extension SetMar 26, 2019
161 days to decisionK182897 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k182897/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Oct 16, 2018
Decision date	Mar 26, 2019
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Velano Vascular
Location	Philadelphia, PA, US
Contact	Tiffini Wittwer
510(k) history	7 submissions · 7 cleared · 2016-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182897/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026