

K190604 PIVOMay 13, 2019
66 days to decisionK190604 · Product code: **JKA** · General Hospital
Source: <https://www.510kdatabase.net/k190604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Mar 8, 2019
Decision date	May 13, 2019
Days to decision	66 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/k190604/> 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