

**K193569 PIVO(TM)**Jan 21, 2020  
29 days to decisionK193569 · Product code: **JKA** · General Hospital  
Source: <https://www.510kdatabase.net/k193569/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Dec 23, 2019
Decision date	Jan 21, 2020
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193569/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026