

**K251518 Volta AF-Xplorer II**Sep 12, 2025  
119 days to decisionK251518 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k251518/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 16, 2025
Decision date	Sep 12, 2025
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Volta Medical</b>
Location	Marseille, FR
Contact	Paola Milpied
510(k) history	5 submissions · 5 cleared · 2020-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Kristin Duggan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251518/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026