

**K201298 VX1**Sep 16, 2020  
124 days to decisionK201298 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k201298/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 15, 2020
Decision date	Sep 16, 2020
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201298/> 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 25, 2026