

**K252972 CARTO™ 3 EP Navigation System V8.4**Feb 20, 2026  
156 days to decisionK252972 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k252972/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 17, 2025
Decision date	Feb 20, 2026
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biosense Webster, Inc.</b>
Location	Irvine, CA, US
Contact	Caleb Lau
Website	<a href="https://www.jnjmedtech.com">https://www.jnjmedtech.com</a>
510(k) history	73 submissions · 73 cleared · 1999-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Biosense Webster, Ltd.</b>
Contact	Dorit Eizenberg

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252972/> 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