

**K173977 CARTO 3 EP Navigation System, Version 4.35 and Accessories with COHERENT MAP Module**Jun 14, 2018  
167 days to decisionK173977 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k173977/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 29, 2017
Decision date	Jun 14, 2018
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173977/> 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 30, 2026