

K133916 CARTO 3 EP NAVIGATION SYSTEM, VERSION 4.2Jul 1, 2014
190 days to decisionK133916 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k133916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 23, 2013
Decision date	Jul 1, 2014
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosense Webster, Inc.
Location	Irvine, CA, US
Contact	WAYNE R HOHMAN
Website	https://www.jnjmedtech.com
510(k) history	73 submissions · 73 cleared · 1999-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133916/> Data sourced from FDA 510(k) public records (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. - Generated June 6, 2026