

K170600 CARTO 3 EP Navigation System, Version 6.0 and AccessoriesJul 25, 2017
146 days to decisionK170600 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k170600/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Mar 1, 2017
Decision date	Jul 25, 2017
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170600/> 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 1, 2026