

K191660 CARTO 3 EP Navigation System, Version 7.1 and AccessoriesJul 20, 2019
29 days to decisionK191660 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k191660/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jun 21, 2019
Decision date	Jul 20, 2019
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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