

K213264 CARTO 3 EP Navigation System Version 7.2Oct 29, 2021
29 days to decisionK213264 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k213264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 30, 2021
Decision date	Oct 29, 2021
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	Khaled Hamad
Website	https://www.jnjmedtech.com
510(k) history	73 submissions · 73 cleared · 1999-2026

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