

K254085 CARTO™ 3 EP Navigation System V9.0 with PIU PlusJan 18, 2026
31 days to decisionK254085 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k254085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 18, 2025
Decision date	Jan 18, 2026
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Biosense Webster, Ltd.
Contact	Elena Goldin

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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