FDA 510(k) Premarket Notification

CLEARED

K252972 CARTO™ 3 EP Navigation System V8.4

Feb 20, 2026
156 days to decision

K252972 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k252972/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 17, 2025
Decision date	Feb 20, 2026
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
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	Dorit Eizenberg

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