

**K231207 CARTO™ 3 EP Navigation System Software V8.0
(FG-5400-00, FG-5400-00U)**Sep 7, 2023
133 days to decisionK231207 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k231207/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Apr 27, 2023
Decision date	Sep 7, 2023
Days to decision	133 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

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