

K173978 CARTO 3 EP Navigation System, Version 5.2 and Accessories with CARTOFINDER ModuleAug 24, 2018
238 days to decisionK173978 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k173978/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Computer, Diagnostic, Programmable (DQK) |
| Date received | Dec 29, 2017 |
| Decision date | Aug 24, 2018 |
| Days to decision | 238 days |
| Third-party review | 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173978/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 30, 2026