

**K072202 CARTO 3 NAVIGATION SYSTEM (MODEL:FG-5400-00),
CARTO 3 EXTERNAL REFERENCE PATCHES
(MODEL:D-1283-01)**Nov 19, 2007
103 days to decisionK072202 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k072202/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Aug 8, 2007
Decision date	Nov 19, 2007
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072202/> 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 June 26, 2026