FDA 510(k) Premarket Notification

K133916 CARTO 3 EP NAVIGATION SYSTEM, VERSION 4.2

CLEARED

Jul 1, 2014
190 days to decision

K133916 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k133916/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 23, 2013
Decision date	Jul 1, 2014
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biosense Webster, Inc.**
Location	Irvine, CA, US
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510(k) history	73 submissions · 73 cleared · 1999-2026