

**K083328 ENSITE SYSTEM, MODEL EE3000, AND ENSITE NAVX
SURFACE ELECTRODE, MODEL EN0010**May 22, 2009
191 days to decisionK083328 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k083328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Nov 12, 2008
Decision date	May 22, 2009
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	St Jude Medical
Location	Minnetonka, MN, US
Contact	KAREN MCKELVEY
Website	http://www.sjm.com/
510(k) history	105 submissions · 105 cleared · 2000-2018

St Jude Medical was a global medical device company headquartered in Little Canada, Minnesota. The company operated more than 20 principal facilities worldwide and sold products in over 100 countries. St Jude Medical received FDA 510(k) clearances from total submissions between 2000 and 2018. The company's regulatory focus centered on Cardiovascular devices, which represented 91% of all submissions. Notable cleared products include cardiac mapping systems, pacing catheters, and mobile cardiac applications. Now part of Abbott Laboratories following its acquisition in Janua...