

**K060954 MODIFICATION TO ENSITE SYSTEM, MODEL EE3000**Apr 21, 2006  
14 days to decisionK060954 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k060954/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Apr 7, 2006
Decision date	Apr 21, 2006
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>St. Jude Medical, Inc.-Endocardial Solutions</b>
Location	St. Paul, MN, US
Contact	KAREN J MCKELVEY
510(k) history	1 submissions · 1 cleared · 2006-2006

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k060954/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026