FDA 510(k) Premarket Notification

K060954 MODIFICATION TO ENSITE SYSTEM, MODEL EE3000

CLEARED

Apr 21, 2006
14 days to decision

K060954 · 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	**St. Jude Medical, Inc.-Endocardial Solutions**
Location	St. Paul, MN, US
Contact	KAREN J MCKELVEY
510(k) history	1 submissions · 1 cleared · 2006-2006