

**K033211 ENSITE SYSTEM**Oct 30, 2003  
27 days to decisionK033211 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k033211/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Oct 3, 2003
Decision date	Oct 30, 2003
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Endocardial Solutions, Inc.</b>
Location	St. Paul, MN, US
Contact	KAREN J MCKELVEY
510(k) history	8 submissions · 4 cleared · 1999-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033211/> 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 July 3, 2026