

**K992479 ENSITE 3000 SYSTEM**Dec 2, 1999  
129 days to decisionK992479 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k992479/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jul 26, 1999
Decision date	Dec 2, 1999
Days to decision	129 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	JAMES W BULLOCK
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/k992479/> 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