

**K012206 ALTERNANAS PROCESSING SYSTEM, CH 2000  
CARDIAC DIAGNOSTIC SYSTEM, HEARTWAVE ALTERNANS  
PROCESSING SYSTEM**Oct 12, 2001  
91 days to decisionK012206 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k012206/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jul 13, 2001
Decision date	Oct 12, 2001
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cambridge Heart, Inc.</b>
Location	South West Ranches, FL, US
Contact	JOHN GREENBAUM
510(k) history	17 submissions · 17 cleared · 1996-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012206/> 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 21, 2026