

**K011324 CAMBRIDGE HEART MODEL CH 2000 CARDIAC
DIAGNOSTIC SYSTEM**May 23, 2001
22 days to decisionK011324 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k011324/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	May 1, 2001
Decision date	May 23, 2001
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011324/> Data sourced from FDA 510(k) public records (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. - Generated June 21, 2026