

K003492 ANALYTIC SPECTRAL METHOD OF ALTERNANS PROCESSINGJan 18, 2001
66 days to decisionK003492 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k003492/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Nov 13, 2000
Decision date	Jan 18, 2001
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary
Other names	CH 2000 CARDIAC DIAGNOSTIC SYSTEM; HEARTWAVE ALTERNANS PROCESSING SYS

APPLICANT

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

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