

**K013564 MODIFICATION TO HEARTWAVE ALTERNANS
PROCESSING SYSTEM, MODEL APS**Nov 21, 2001
26 days to decisionK013564 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k013564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph (DPS)
Date received	Oct 26, 2001
Decision date	Nov 21, 2001
Days to decision	26 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/k013564/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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