

**K981697 CAMBRIDGE HEART CH 2000 CARDIAC DIAGNOSTIC SYSTEM**Oct 14, 1998  
156 days to decisionK981697 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k981697/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	May 11, 1998
Decision date	Oct 14, 1998
Days to decision	156 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981697/>. 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