

**K010758 HEARTWAVE ALTERNANS PROCESSING SYSTEM,  
APS**Apr 12, 2001  
30 days to decisionK010758 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k010758/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Electrocardiograph (DPS)           |
| Date received         | Mar 13, 2001                       |
| Decision date         | Apr 12, 2001                       |
| Days to decision      | 30 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/k010758/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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