

K002197 CARTOUCHDec 27, 2000
160 days to decisionK002197 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k002197/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Electrocardiograph (DPS) |
| Date received | Jul 20, 2000 |
| Decision date | Dec 27, 2000 |
| Days to decision | 160 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cardionics, Inc. |
| Location | Houston, TX, US |
| Contact | JEFF MORGAN |
| 510(k) history | 2 submissions · 2 cleared · 1986-2000 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002197/> 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 July 3, 2026