

**K072217 ECG-1250A SERIES CARDIOFAX S AND ECG-1350A
SERIES CARDIOFAX M**Aug 30, 2007
21 days to decisionK072217 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k072217/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Electrocardiograph (DPS) |
| Date received | Aug 9, 2007 |
| Decision date | Aug 30, 2007 |
| Days to decision | 21 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nihon Kohden America, Inc. |
| Location | Foothill Ranch, CA, US |
| Contact | JACK COGGAN |
| 510(k) history | 166 submissions · 163 cleared · 1979-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072217/>; 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 May 24, 2026