

K860827 EM STRESS ELECTRODEMay 8, 1986
64 days to decisionK860827 · Product code: **DRX** · CardiovascularSource: <https://www.510kdatabase.net/k860827/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Electrocardiograph (DRX) |
| Date received | Mar 5, 1986 |
| Decision date | May 8, 1986 |
| Days to decision | 64 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Electromed Intl., Ltd. |
| Location | Mchenry, IL, US |
| Contact | MEGAN J MACAULEY |
| 510(k) history | 23 submissions · 23 cleared · 1981-2001 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860827/>; 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 19, 2026