

K812674 INFANT CARIDAC MONITOROct 13, 1981
21 days to decisionK812674 · Product code: **DRT** · CardiovascularSource: <https://www.510kdatabase.net/k812674/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT) |
| Date received | Sep 22, 1981 |
| Decision date | Oct 13, 1981 |
| Days to decision | 21 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k812674/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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