

K821791 EXTERNAL PULSE GENERATOR - EV4542Jul 6, 1982
19 days to decisionK821791 · Product code: **DTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k821791/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pulse-generator, Pacemaker, External (DTE) |
| Date received | Jun 17, 1982 |
| Decision date | Jul 6, 1982 |
| Days to decision | 19 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | American Pacemaker Corp. |
| Location | Mchenry, IL, US |
| 510(k) history | 14 submissions · 14 cleared · 1977-1982 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k821791/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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