

K811092 STERILE PACKAGINGJul 1, 1981
71 days to decisionK811092 · Product code: **DTE** · CardiovascularSource: <https://www.510kdatabase.net/k811092/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pulse-generator, Pacemaker, External (DTE) |
| Date received | Apr 21, 1981 |
| Decision date | Jul 1, 1981 |
| Days to decision | 71 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Telectronics, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 107 submissions · 107 cleared · 1977-1990 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k811092/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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