

K823197 MODEL 8300 TESTERDec 30, 1982
65 days to decisionK823197 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k823197/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT) |
| Date received | Oct 26, 1982 |
| Decision date | Dec 30, 1982 |
| Days to decision | 65 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Medicon, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 14 submissions · 14 cleared · 1981-1997 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k823197/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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