

K802900 HEART SENTINELMar 11, 1981
114 days to decisionK802900 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k802900/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Detector And Alarm, Arrhythmia (DSI) |
| Date received | Nov 17, 1980 |
| Decision date | Mar 11, 1981 |
| Days to decision | 114 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Totemite Medical Electronics |
| Location | Mchenry, IL, US |
| 510(k) history | 2 submissions · 2 cleared · 1981-1987 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k802900/> 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 July 7, 2026