FDA 510(k) Premarket Notification

# K823586 COMPUTER-AIDED ELECTROCARDIOGRAPH FCP200

**CLEARED**

Apr 6, 1983
121 days to decision

K823586 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k823586/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Detector And Alarm, Arrhythmia (DSI) |
| Date received | Dec 6, 1982 |
| Decision date | Apr 6, 1983 |
| Days to decision | 121 days |
| Third-party review | No |

## APPLICANT

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|---|---|
| Company | **Brentwood Instruments, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 21 submissions · 20 cleared · 1981-1990 |