FDA 510(k) Premarket Notification

# K781911 ECG ANALYZER, HIGH SPEED

**CLEARED**

Nov 30, 1978
16 days to decision

K781911 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k781911/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Detector And Alarm, Arrhythmia (DSI) |
| Date received | Nov 14, 1978 |
| Decision date | Nov 30, 1978 |
| Days to decision | 16 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Cardio-Dynamics Laboratories, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 4 submissions · 4 cleared · 1977-1978 |