FDA 510(k) Premarket Notification

# K822968 ELECTROCARDIOGRAPH INTERPRETER

**CLEARED**

Dec 15, 1982
69 days to decision

K822968 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k822968/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Detector And Alarm, Arrhythmia (DSI) |
| Date received | Oct 7, 1982 |
| Decision date | Dec 15, 1982 |
| Days to decision | 69 days |
| Third-party review | No |

## APPLICANT

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|---|---|
| Company | **Suzuken Co., Ltd.** |
| Location | Walker, MI, US |
| 510(k) history | 13 submissions · 13 cleared · 1981-2018 |