FDA 510(k) Premarket Notification

# K822319 RE1000 HEART RATE MONITOR

**CLEARED**

Sep 14, 1982
42 days to decision

K822319 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k822319/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT) |
| Date received | Aug 3, 1982 |
| Decision date | Sep 14, 1982 |
| Days to decision | 42 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Electronic Monitors, Inc.** |
| Location | Walker, MI, US |
| 510(k) history | 3 submissions · 3 cleared · 1982-1993 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k822319/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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