FDA 510(k) Premarket Notification

# K782089 MONITOR, HEART RATE MODEL 103

**CLEARED**

Jan 4, 1979
21 days to decision

K782089 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k782089/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT) |
| Date received | Dec 14, 1978 |
| Decision date | Jan 4, 1979 |
| Days to decision | 21 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Roche Medical Electronics, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 16 submissions · 16 cleared · 1976-1979 |