FDA 510(k) Premarket Notification

# K993788 R.TEST EVOLUTION

**CLEARED**

Aug 4, 2000
269 days to decision

K993788 · Product code: **MLO** · Cardiovascular
Source: https://www.510kdatabase.net/k993788/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO) |
| Date received | Nov 9, 1999 |
| Decision date | Aug 4, 2000 |
| Days to decision | 269 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Novacor Div.** |
| Location | Flemington, NJ, US |
| Contact | LYNETTE L HOWARD |
| 510(k) history | 1 submissions · 1 cleared · 2000-2000 |