FDA 510(k) Premarket Notification

# K770212 PROLITH MODEL 21S CARDIAC PULSE GEN.

**CLEARED**

Mar 9, 1977
37 days to decision

K770212 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k770212/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implantable Pacemaker Pulse-generator (DXY) |
| Date received | Jan 31, 1977 |
| Decision date | Mar 9, 1977 |
| Days to decision | 37 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Edwards Pacemaker Systems** |
| Location | Mchenry, IL, US |
| 510(k) history | 13 submissions · 13 cleared · 1977-1979 |