

K770212 PROLITH MODEL 21S CARDIAC PULSE GEN.Mar 9, 1977
37 days to decisionK770212 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k770212/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| 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 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k770212/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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