FDA 510(k) Premarket Notification

# K801810 PACEMAKER PATIENT MGMT. SYSTEM

**CLEARED**

Feb 5, 1981
190 days to decision

K801810 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k801810/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Computer, Diagnostic, Programmable (DQK) |
| Date received | Jul 30, 1980 |
| Decision date | Feb 5, 1981 |
| Days to decision | 190 days |
| Third-party review | No |

## APPLICANT

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|---|---|
| Company | **Siemens Elema AB** |
| Location | Mchenry, IL, US |
| 510(k) history | 63 submissions · 60 cleared · 1978-2003 |