

K802864 SIEMENS-ELEMA PULSE GENERATOR 678Feb 5, 1981
85 days to decisionK802864 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k802864/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implantable Pacemaker Pulse-generator (DXY) |
| Date received | Nov 12, 1980 |
| Decision date | Feb 5, 1981 |
| Days to decision | 85 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k802864/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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