FDA 510(k) Premarket Notification

# K830344 SIEMENS-ELMA PULSE GENERATOR #718

**CLEARED**

May 27, 1983
114 days to decision

K830344 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k830344/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implantable Pacemaker Pulse-generator (DXY) |
| Date received | Feb 2, 1983 |
| Decision date | May 27, 1983 |
| Days to decision | 114 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Burditt & Calkins-Siemens-Elema** |
| Location | Mchenry, IL, US |
| 510(k) history | 10 submissions · 10 cleared · 1976-1984 |