

K854560 IMPLANTABLE PROGRAMMABLE PULSE GENERATORJan 16, 1986
63 days to decisionK854560 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k854560/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implantable Pacemaker Pulse-generator (DXY) |
| Date received | Nov 14, 1985 |
| Decision date | Jan 16, 1986 |
| Days to decision | 63 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Telectronics, Inc. |
| Location | Mchenry, IL, US |
| Contact | WILLIAM C NEALON |
| 510(k) history | 107 submissions · 107 cleared · 1977-1990 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k854560/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 22, 2026