FDA 510(k) Premarket Notification

# K781090 GENERATOR, CARDIAC PULSE, 250B

**CLEARED**

Sep 7, 1978
66 days to decision

K781090 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k781090/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implantable Pacemaker Pulse-generator (DXY) |
| Date received | Jul 3, 1978 |
| Decision date | Sep 7, 1978 |
| Days to decision | 66 days |
| Third-party review | No |

## APPLICANT

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