FDA 510(k) Premarket Notification

K780940 GENERATOR, PULSE, MODEL 160B

CLEARED

Sep 27, 1978
111 days to decision

K780940 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k780940/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 8, 1978
Decision date	Sep 27, 1978
Days to decision	111 days
Third-party review	No

APPLICANT

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