FDA 510(k) Premarket Notification

K771670 IMPLANTED PACEMAKER PLUSE GENERATOR

CLEARED

Sep 12, 1977
11 days to decision

K771670 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k771670/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Sep 1, 1977
Decision date	Sep 12, 1977
Days to decision	11 days
Third-party review	No

APPLICANT

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