FDA 510(k) Premarket Notification

K850252 QMPLANTABLE PROGRAM. CARDIAC PULSE GEN. W/TELEMETR

CLEARED

Apr 4, 1985
72 days to decision

K850252 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k850252/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 22, 1985
Decision date	Apr 4, 1985
Days to decision	72 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