FDA 510(k) Premarket Notification

K881837 OPTIMA MPT SERIES III PACEMAKER, 5281D AND 5282D

CLEARED

Jul 18, 1988
77 days to decision

K881837 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k881837/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	May 2, 1988
Decision date	Jul 18, 1988
Days to decision	77 days
Third-party review	No

APPLICANT

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