FDA 510(k) Premarket Notification

K781738 PACEMAKER, MODEL 229-01

CLEARED

Dec 7, 1978
51 days to decision

K781738 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k781738/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Oct 17, 1978
Decision date	Dec 7, 1978
Days to decision	51 days
Third-party review	No

APPLICANT

Company	**Intermedics, Inc.**
Location	Mchenry, IL, US
510(k) history	211 submissions · 201 cleared · 1977-1996

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k781738/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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