FDA 510(k) Premarket Notification

K792580 PACEMAKER PROGRAMMER

CLEARED

Dec 19, 1979
5 days to decision

K792580 · Product code: **KRG** · Cardiovascular
Source: https://www.510kdatabase.net/k792580/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Programmer, Pacemaker (KRG)
Date received	Dec 14, 1979
Decision date	Dec 19, 1979
Days to decision	5 days
Third-party review	No

APPLICANT

Company	**Cardiac Pacemakers, Inc.**
Location	Mchenry, IL, US
510(k) history	76 submissions · 76 cleared · 1977-2010

Cardiac Pacemakers, Inc. (CPI), doing business as Guidant Cardiac Rhythm Management, manufactured implantable cardiac rhythm management devices. Now part of Boston Scientific, the company is based in Saint Paul, Minnesota, with historical operations in McHenry, US. The company received FDA 510(k) clearances from total submissions between 1977 and 2010. Cardiovascular devices dominated the regulatory portfolio at 83% of submissions. This historical record reflects the company's core focus on cardiac rhythm management and related interventional technologies. CPI developed t...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k792580/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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