FDA 510(k) Premarket Notification

K800026 MICROTHIN-DI

CLEARED

Jan 31, 1980
24 days to decision

K800026 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k800026/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 7, 1980
Decision date	Jan 31, 1980
Days to decision	24 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...

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Device record: https://www.510kdatabase.net/k800026/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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