

K802353 MICRO THIN-PII, #0523Dec 22, 1980
88 days to decisionK802353 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k802353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Sep 25, 1980
Decision date	Dec 22, 1980
Days to decision	88 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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