

**K802089 CARDIOTRAK**Sep 26, 1980  
24 days to decisionK802089 · Product code: **DXH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k802089/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Sep 2, 1980
Decision date	Sep 26, 1980
Days to decision	24 days
Third-party review	No

**APPLICANT**

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Company	<b>Cardiac Pacemakers, Inc.</b>
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...