

**K811774 OPEN LOOP AMBULATORY INFUSION DEVICE**Jul 10, 1981  
17 days to decisionK811774 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k811774/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jun 23, 1981
Decision date	Jul 10, 1981
Days to decision	17 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...

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