

K872774 BETATRON IV SYSTEMJan 5, 1988
175 days to decisionK872774 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k872774/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jul 14, 1987
Decision date	Jan 5, 1988
Days to decision	175 days
Third-party review	No

APPLICANT

Company	Cardiac Pacemakers, Inc.
Location	Mchenry, IL, US
Contact	MULLIS, JR.
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...
