FDA 510(k) Premarket Notification

K823204 BETATRON II

CLEARED

Nov 30, 1982
34 days to decision

K823204 · Product code: **FRN** · General Hospital
Source: https://www.510kdatabase.net/k823204/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Oct 27, 1982
Decision date	Nov 30, 1982
Days to decision	34 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/k823204/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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