

K842394 ASTRA 2, ASTRA 3, 4 & 6Oct 17, 1984
120 days to decisionK842394 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k842394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 19, 1984
Decision date	Oct 17, 1984
Days to decision	120 days
Third-party review	No

APPLICANT

Company	Cardiac Pacemakers, Inc.
Location	Mchenry, IL, US
Contact	ANN MORRISSEY
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...
