

K863000 ASTRA 2,3,4 AND 6: CHIP REVISIONAug 19, 1986
11 days to decision

K863000 - Cardiovascular

Source: <https://www.510kdatabase.net/k863000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Aug 8, 1986
Decision date	Aug 19, 1986
Days to decision	11 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...