

K811401 COMMAND P5(UNIPOLAR PULSE GENERATOR)Jul 27, 1981
69 days to decision

K811401 · Cardiovascular

Source: <https://www.510kdatabase.net/k811401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	May 19, 1981
Decision date	Jul 27, 1981
Days to decision	69 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...