

**K831216 COMMAND ULTRA II**Jul 12, 1983  
89 days to decisionK831216 · Product code: **DXY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k831216/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 14, 1983
Decision date	Jul 12, 1983
Days to decision	89 days
Third-party review	No

**APPLICANT**

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Company	<b>Cardiac Pacemakers, Inc.</b>
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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