

**K875147 TORQUE HEX WRENCH**Jan 27, 1988  
43 days to decisionK875147 · Product code: **DTF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k875147/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tools, Pacemaker Service (DTF)
Date received	Dec 15, 1987
Decision date	Jan 27, 1988
Days to decision	43 days
Third-party review	No

**APPLICANT**

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Company	<b>Cardiac Pacemakers, Inc.</b>
Location	Mchenry, IL, US
Contact	GREG MATHISON
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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