

K080154 ACUITY UNIVERSAL CUTTERMar 20, 2008
57 days to decisionK080154 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k080154/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 23, 2008
Decision date	Mar 20, 2008
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiac Pacemakers, Inc.
Location	Mchenry, IL, US
Contact	KATHLEEN VITTUM
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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