FDA 510(k) Premarket Notification

K093969 ACUITY BREAK-AWAY GUIDE CATHETER

CLEARED

Mar 5, 2010
72 days to decision

K093969 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k093969/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 23, 2009
Decision date	Mar 5, 2010
Days to decision	72 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...