

K120296 CPS DIRECT MEDIGUIDE ENABLED OUTER CATHETERMay 11, 2012
101 days to decisionK120296 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k120296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 31, 2012
Decision date	May 11, 2012
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	St. Jude Medical, Cardiac Rhythm Management Divisi
Location	Sylmar, CA, US
Contact	COLLEEN CANAN
510(k) history	10 submissions · 10 cleared · 2008-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120296/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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