

**K061710 CPS DIRECT PL PEELABLE OUTER GUIDE
CATHETER**Jul 14, 2006
25 days to decisionK061710 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k061710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 19, 2006
Decision date	Jul 14, 2006
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary
Other names	ACCESSORY, VALVE BYPASS TOOLS

APPLICANT

Company	St Jude Medical
Location	Minnetonka, MN, US
Contact	ADELE SHOUSTAL
Website	http://www.sjm.com/
510(k) history	105 submissions · 105 cleared · 2000-2018

St Jude Medical was a global medical device company headquartered in Little Canada, Minnesota. The company operated more than 20 principal facilities worldwide and sold products in over 100 countries. St Jude Medical received FDA 510(k) clearances from total submissions between 2000 and 2018. The company's regulatory focus centered on Cardiovascular devices, which represented 91% of all submissions. Notable cleared products include cardiac mapping systems, pacing catheters, and mobile cardiac applications. Now part of Abbott Laboratories following its acquisition in Janua...