

K103250 CPS DIRECT SL II SLITTABLE OUTER CATHETERJan 19, 2011
77 days to decisionK103250 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k103250/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Nov 3, 2010
Decision date	Jan 19, 2011
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

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

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