

K100135 GDS-DC12Apr 16, 2010
87 days to decisionK100135 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k100135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 19, 2010
Decision date	Apr 16, 2010
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guided Delivery Systems
Location	Santa Clara, CA, US
Contact	BONNIE L MCINERNEY
510(k) history	2 submissions · 2 cleared · 2009-2010

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