

**K130378 RESPIGUIDE DELIVERY SYSTEM**Oct 17, 2013  
245 days to decisionK130378 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k130378/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 14, 2013
Decision date	Oct 17, 2013
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Respocardia</b>
Location	Minnetonka, MN, US
Contact	BONNIE LABOSKY
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130378/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 8, 2026