

**K131492 MODIFIED FLOWGATE BALLOON GUIDE CATHETER**Oct 3, 2013  
133 days to decisionK131492 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k131492/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 23, 2013
Decision date	Oct 3, 2013
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Concentric Medical, Inc.</b>
Location	Moutian View, CA, US
Contact	RHODA SANTOS
510(k) history	45 submissions · 44 cleared · 2001-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131492/> 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 May 14, 2026