

**K122917 CODA BALLOON CATHETER**Jun 28, 2013  
276 days to decisionK122917 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k122917/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 25, 2012
Decision date	Jun 28, 2013
Days to decision	276 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook, Inc.</b>
Location	Mchenry, IL, US
Contact	ELYSIA EASTON
510(k) history	190 submissions · 179 cleared · 1976-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122917/> 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