

**K093866 EVALVE STEERABLE GUIDE CATHETER**Jan 13, 2010  
27 days to decisionK093866 · Product code: **DRA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k093866/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Steerable (DRA)
Date received	Dec 17, 2009
Decision date	Jan 13, 2010
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Evalve, Inc.</b>
Location	Menlo Park, CA, US
Contact	SEVRINA CIUCCI
510(k) history	4 submissions · 4 cleared · 2009-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093866/> 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 21, 2026