

K083793 STEERABLE GUIDE CATHETERApr 27, 2009
126 days to decisionK083793 · Product code: **DRA** · CardiovascularSource: <https://www.510kdatabase.net/k083793/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Steerable (DRA)
Date received	Dec 22, 2008
Decision date	Apr 27, 2009
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Evalve, Inc.
Location	Menlo Park, CA, US
Contact	KARUNA VELUSAMY
510(k) history	4 submissions · 4 cleared · 2009-2010

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