

K091596 EVALVE STEERABLE GUIDE CATHETER, MODEL SGC01STJul 2, 2009
30 days to decisionK091596 · Product code: **DRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k091596/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Steerable (DRA)
Date received	Jun 2, 2009
Decision date	Jul 2, 2009
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091596/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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