

**K100789 MODIFICATON TO: STEERABLE GUIDE CATHETER,
MODEL SGC01ST**

Apr 21, 2010
30 days to decision

K100789 · Product code: **DRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k100789/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Steerable (DRA)
Date received	Mar 22, 2010
Decision date	Apr 21, 2010
Days to decision	30 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k100789/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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