FDA 510(k) Premarket Notification

K100789 MODIFICATON TO: STEERABLE GUIDE CATHETER, MODEL SGC01ST

CLEARED

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