FDA 510(k) Premarket Notification

K083793 STEERABLE GUIDE CATHETER

CLEARED

Apr 27, 2009
126 days to decision

K083793 · Product code: **DRA** · Cardiovascular
Source: 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