FDA 510(k) Premarket Notification

# K112239 STEERABLE GUIDE CATHETER

**CLEARED**

Aug 31, 2011
27 days to decision

K112239 · Product code: **DRA** · Cardiovascular
Source: https://www.510kdatabase.net/k112239/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Steerable (DRA) |
| Date received | Aug 4, 2011 |
| Decision date | Aug 31, 2011 |
| Days to decision | 27 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Abbott Vascular** |
| Location | S,Mta Clara, CA, US |
| Contact | CYNTHIA MORROW |
| 510(k) history | 30 submissions · 30 cleared · 2009-2022 |