

K092286 FOX SV PTA CATHETERAug 27, 2009
29 days to decisionK092286 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k092286/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received | Jul 29, 2009 |
| Decision date | Aug 27, 2009 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092286/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026