

K080264 MODIFICATION TO: FOX PLUS PTA CATHETERMar 26, 2008
54 days to decisionK080264 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k080264/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received | Feb 1, 2008 |
| Decision date | Mar 26, 2008 |
| Days to decision | 54 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Abbott Vascular-Vascular Solutions |
| Location | S,Mta Clara, CA, US |
| Contact | Ivalee Cohen |
| 510(k) history | 6 submissions · 5 cleared · 2008-2009 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080264/> 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 14, 2026