

K162322 the POWERWAND Safety Introducer with an Extended Dwell Catheter, 3Fr. ModelNov 17, 2016
90 days to decisionK162322 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k162322/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Aug 19, 2016 |
| Decision date | Nov 17, 2016 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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|----------------|---------------------------------------|
| Company | Access Scientific, LLC |
| Location | San Diego, CA, US |
| Contact | WALTER CORDIGLIA |
| 510(k) history | 6 submissions · 6 cleared · 2013-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162322/> 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 June 28, 2026